UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA, New York, N.Y.

v. 13 Cr. 0794(AT)

PAUL WISEBERG and ROBERT KALABA,

Defendants.

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October 14, 2015
8:59 a.m.

Before:

HON. ANALISA TORRES,

District Judge

APPEARANCES

PREET BHARARA
United States Attorney for the
Southern District of New York
BY: DANIEL B. TEHRANI
EDWARD B. DISKANT
SHAWN G. CROWLEY
Assistant United States Attorneys

NEIL B. CHECKMAN
SAM A. SCHMIDT
KAREN H. CHARRINGTON
Attorneys for Defendant Paul Wiseberg

DAVID N. FISHER
JANE H. FISHER-BYRIALSEN
Attorneys for Defendant Robert Kalaba

- also present -

Elizabeth Joynes, Government Paralegal
Task Force Officer Brian Hammarstrom

WILLIAM WINSLEY,

called as a witness by the government,

having been duly sworn, testified as follows:

THE CLERK: Would you please state your name and spell it for the record.

THE WITNESS: William D. Winsley, W-i-n, as in Nancy, s-l-e-y.

THE CLERK: Thank you.

THE COURT: You may inquire.

DIRECT EXAMINATION

BY MR. TEHRANI:

Q. Good morning, Mr. Winsley.

A. Good morning.

Q. How are you employed?

A. Well, I'm now retired. I'm a pharmacist by training. I worked as a pharmacist for 14 years and then I worked for the Ohio State Board of Pharmacy. The last 13 years I was there, I was the Executive Director of the Board.

Q. And when did you retire?

A. The end of 2011.

Q. What have you been doing since then?

A. Well, I have been doing consulting. I have now been giving talks around the country along with DEA and other talks as well.

Q. Could you please describe your educational background?

A. Yes. I have a bachelor's degree in pharmacy and a master's degree in hospital pharmacy administration, both from the Ohio State University. During my bachelor's process I did an internship at the pharmacy owned by my mother and father, who were both pharmacists. So I had the on-the-job training that was required for licensure. And then after my master's degree, I served a residency at Riverside Methodist Hospital in Columbus, Ohio.

Q. Did you ever become a licensed pharmacist?

A. I did. In 1974, after I graduated with my bachelor's degree, I took the licensure examinations to become a pharmacist and passed them.

Q. Can you describe the licensure examination a little bit?

A. Yes. Pharmacists take two examinations. One is a clinical exam to test knowledge of drugs, disease states, uses of drugs in disease states, doses, and things like that. The second examination is a law exam on drug laws, both state and federal.

Q. Then I think you testified that you were a practicing pharmacist for approximately 14 years?

A. Yes. I worked in primarily hospitals for 14 years before I joined the Board of Pharmacy.

Q. And what was your role initially when you joined the Board of Pharmacy?

A. I joined the Board first as a compliance specialist, which meant I was a pharmacist in the field doing inspections and

investigations. The Board of Pharmacy in Ohio is not only a licensing agency but is also a law enforcement agency. Since Ohio does not have a state police, so the Pharmacy Board was charged with enforcing the criminal drug laws as well. So I did investigations of not only pharmacists, pharmacy interns, but also doctors, nurses, general public, and I also then did inspections of all licensed sites. That was when I was a compliance specialist.

Two years later I was brought into the office as Assistant Executive Director, and then seven years after that, in 1998, when my predecessor retired, I was appointed by the Board to be the Executive Director, and I served as Exec for 13 years until I retired

Q. Could you describe some of your duties and responsibilities as Executive Director of Ohio Board of Pharmacy?

A. As the Executive Director, I was, of course, responsible for the operation of the Board, which meant I oversaw all of the day-to-day operations, including the field staff and their investigations and inspections. I was responsible for developing the budget, presenting it to the legislature and the governor, of course, and basically answering phone calls with questions from practitioners, not only pharmacists but doctors, veterinarians, dentists. We got a lot of phone calls with questions about drug laws, and so a lot of my day was taken up with answering those.

Q. Did you have any affiliation with the National Association of Boards of Pharmacy?
A. Yes. The National Association of Boards of Pharmacy, more commonly called "NABP", is an association of all of the boards of pharmacy not only in the United States but also some outside of the United States as well. It is an association that was set up to assist the Boards in carrying out their mission, which is primarily protect the health and safety of patients. And during my tenure as Executive Director, I spent four years on the NABP Executive Committee, which is their way of calling it; that's what they called their Board of Directors. Then I became Treasurer of NABP. The next year I was President Elect, then President and then Chairman of the Executive Committee, Chairman of the Board. I finished that role as Chairman in May of 2012.
Q. Have you published in the field of pharmacy practice?
A. Well, the Board of Pharmacy publishes a quarterly -- excuse me -- publishes a quarterly newsletter that goes out to all of our licensees plus other people who have asked to be put on the mailing list, and I was responsible, as Executive Director, for writing that newsletter, and I did that continuously from -- actually, the first one would have been February of 1999 until I retired at the end of 2011.
Q. Can you describe some of the topics that you might have covered or that you covered in some of your publications?

A. Yes. Quite frequently, over the years I would revisit the issue of corresponding responsibility of pharmacists and physicians, which I think we'll get into later. I also covered other practice-related issues that came about because of questions I would receive.

We are responsible, of course, for making the rules that govern the practice of pharmacy as well as some in medicine, dentistry and nursing. So anytime there were changes to the rules I would also write those so that pharmacists that got our newsletter would be kept up to date on changes to the law. And I addressed other practice-related issues, electronic prescribing and prescriptions when that was relatively new. When nurse practitioners got prescribing, we covered their rules and regs. So, generally, a broad range of topics but all of them related in one way or the other to the practice of pharmacy.

Q. Have you spoken in the field of pharmacy practice?

A. Yes. I've given well over 500 talks, both State of Ohio and nationally, to a variety of groups, pharmacists, physicians, nurses, veterinarians, dentists, general public, just about all of them on drug laws, rules and regulations as they relate to the particular practice that I was addressing.

Q. Do you speak at any pharmacy continuing education seminars?

A. Yes. In addition to those talks, most of which were continuing education, at least the pharmacy talks that I gave,

since I retired, I have been going around the country with DEA doing pharmacy diversion awareness conferences where we go into a state, and the pharmacists gather and we have a day-long seminar that we present to the pharmacists on various practice-related issues. My assignment at these is to talk to them as one pharmacist to a group on what corresponding responsibility really means and give them some examples of cases that demonstrate that issue and talk about a few other practice-related issues like prescription monitoring programs and so forth.

Q. Have you testified before any legislative bodies on the subject of pharmacy practice?

A. Yes. I've as Executive Director -- well, as Assistant Executive Director and Executive Director, I have had a large amount of contact with our state legislature in Ohio. Most any bill that involved drug laws and some drug therapy issues, we were either consulted about or we would go over and initiate the discussion. I testified numerous times on bills in front of the Ohio legislature. In addition to that, I did testify in front of a Congress -- a Congressional committee on the Ryan Haight Act, which was a bill to deal with the Internet drug problem.

Q. Have you testified in any court proceedings as an expert in the field of pharmacy practice?

A. I have testified during my tenure as a compliance

specialist. As I said, I was involved in criminal investigations as well as administrative ones, and I testified numerous times in state criminal court on those cases that either I had investigated myself or that I was brought in as a pharmacist expert by the other agents in order to testify. In addition, I have testified twice in federal court. This will be my third time. So, yes, I've testified in court hearings as well as administrative hearings.

MR. TEHRANI: Your Honor, at this time we move to qualify Mr. Winsley as an expert in the field of professional standards relating to pharmacy practice.

THE COURT: Any objection?

MR. FISHER: No objection.

MR. SCHMIDT: If I may, your Honor?

THE COURT: All right.

VOIR DIRE EXAMINATION

BY MR. SCHMIDT:

Q. You were involved in setting standards in the State of Ohio, is that right?

A. As Executive Director, yes. In my role with NABP, we developed standards that are to be used by states nationwide.

Q. Those rules nationwide are suggestions to individual state board of pharmacies?

A. They are model pharmacy rules and laws, yes, sir.

MR. SCHMIDT: Your Honor, with only the limitation

that his expertise I believe covers the State of Ohio and general expertise but only in the State of Ohio -- I withdraw. I have no objection.

THE COURT: I so qualify him.

DIRECT EXAMINATION (Resumed)

BY MR. TEHRANI:

Q. Mr. Winsley, in what city are you based?

A. I now live in a town called Millfield, Ohio since I have retired. The Board of Pharmacy was based in Columbus, Ohio, and that's where I worked during my tenure with the Board.

Q. And who paid for your travel to New York and your accommodations while you are here?

A. The U.S. Attorney's Office.

Q. And are you being compensated by the government in any other way?

A. I am being compensated for work performed.

Q. And how much are you being compensated?

A. $250 an hour for work actually performed plus, of course, travel expenses here and back home.

Q. Mr. Winsley, are pharmacies regulated?

A. Yes. Pharmacies are very highly regulated. They are regulated federally primarily by the DEA, the Drug Enforcement Administration, and the Food and Drug Administration, the FDA, but primarily they are regulated by their individual state boards of pharmacy where the practice rules and regulations are

documented. Of course, they are also regulated by a lot of, you know, health departments and local tax authorities and so forth. But the primary regulators of pharmacy practice are the state boards of pharmacy, the DEA and the Food and Drug Administration.

Q. Are you familiar with the term "controlled substance"?

A. Yes, I am. A controlled substance is a drug that is subject to either abuse or addiction potential or both. Controlled substances are divided into five schedules, Schedule I through Schedule V. Schedule I controlled substances are those that are what we term illicit drugs, the street drugs, that have no medicinal use, drugs like heroin, LSD, and several others of a stimulant variety.

Schedules II through V all have medical uses, but Schedule II has the highest addiction liability or abuse potential plus a medical use, all the way down then it diminishes until Schedule V drugs, which have lowest of the controlled substances in terms of abuse and addiction potential.

Q. Can you describe to the jury what oxycodone is?

A. Oxycodone is a pain medication, an opiate, that is a Schedule II controlled substance because of its high degree of abuse potential and addiction liability, but it also has a medicinal use in the treatment of pain.

Q. Based on your training and experience, what risks are

associated with oxycodone usage?
A. Well, primarily addiction to the drug. Overdoses of the drug can lead to respiratory arrest, which means you quit breathing and you die if you don't get treatment in a hurry. But those are the two worst, the addiction being something that's very prevalent in this country.
Q. Is oxycodone chemically similar to any Schedule I controlled substance?
A. Well, it's an opiate, as is heroin. And because of the cost on the street of oxycodone, we now have a problem with a lot of patients transferring from oxycodone to heroin because heroin on the street right now is a whole lot cheaper.
Q. Are there different types and dosages of oxycodone?
A. Yes. There are both what we call immediate release, which are drugs -- think of an aspirin tablet. You take it, it dissolves, it gets into the bloodstream right away, and hopefully it takes care of your headache or whatever pain. And then there are forms that are long-acting, controlled release where you take a dose and it dissolves slowly and releases drug slowly into your system so that you don't have to take it quite so often -- once every 12 hours, for example, versus one every four to six for an immediate release. And oxycodone is available in both forms.
Q. And can you describe some of the immediate release forms of oxycodone?

A. Well, there are several strengths of immediate release. The two most popular, if you will, on the street are oxycodone 15-milligram and 30-milligram immediate release. Those have replaced the former drug that was very popular, which was OxyContin, when it first came out, and now the oxycodone immediate release seems to be the drug of choice that's being abused more.

Q. We'll get to OxyContin in a moment, but are you also familiar with Percocet?

A. Yes. Percocet also contains oxycodone, but it's mixed with acetaminophen, or Tylenol, so it is a combination product. It's also lower strength than most of the oxycodone pure that's available.

Q. Do you know what Roxicodone is?

A. It's oxycodone. It is a brand name.

Q. So you mentioned a little bit about OxyContin. What is OxyContin?

A. Well, OxyContin -- excuse me --

Q. Bless you.

A. Thank you. OxyContin is a form of oxycodone, but it's a sustained release, prolong release dosage form that was released in the '90s, the idea being that it was to be used for patients who had been on pain medication for a while whose dosage was pretty well stabilized but they didn't want to take so many doses during the day. OxyContin when it first came out

became very popular on the street because the way it was manufactured, the tablets could be crushed and then either dissolved and injected, snorted like cocaine, smoked. There are a variety of ways to abuse it. The problem being that you are talking potentially 80 milligrams of oxycodone and that's potentially a lethal dose all at once in somebody who is not used to it.

So a few years after it came out, the drug company did revise their formulation. They made it into a tamper-proof substance. You could no longer smash it and snort it, smash it and then inject it. The only way that it is abusable now is to take it orally and obviously take more than you are supposed to. But that's what led to the increase in the immediate release oxycodone 15s and 30s.

Q. So you have been talking about things like crushing oxycodone, snorting oxycodone. Is that a form of diversion?

A. Yes, it is. The oxycodone was prepared to be taken by mouth. That was the only way it was intended to be taken, and so when it's used outside of the normal channels of distribution and use outside of adequate medical advice, that would be a form of diversion of drugs.

Q. And in your experience, are you aware of whether oxycodone is a controlled substance that is typically diverted?

A. Yes, it is. In many states oxycodone is second only to hydrocodone and in some states it is rapidly overtaking

hydrocodone as being the popular drug on the street.
Q. Can you just describe a little bit what it means for oxycodone to be diverted?
A. I'm not sure. Can you rephrase that? I'm sorry.
Q. Let me ask you a better question.
How does oxycodone get diverted?
A. OK. Thank you. That I understand.
There are a variety of ways that oxycodone gets out to be abused. One is that we have doctors who will write prescriptions for cash. They are not doing the normal doctor things that our doctors all do to us. They don't do all the indignities of the poking, prodding, nosy questions. That it's basically what drug do you want, how much money do you have.
We also have pharmacies that will sell the drug knowing that the prescriptions were bad. We have drugs that get stolen and are then available on the street. And so it gets diverted quite a few ways.
Surveys done by the federal government and the White House National Drug Control Group have shown that the most common way that our kids get ahold of drugs is out of the medicine cabinet, either their own or their friends', but, of course, that begs the question how did they get in the medicine cabinet in the first place, and that was due to either illegal prescribing or overprescribing on the part of the various prescribers.

Q. And you mentioned the fact that diverted oxycodone can find its way onto the street. Is there a black market for diverted oxycodone?
A. Well, selling it on the street basically is a black market. If it's sold any way other than the doctor writes the prescription, the pharmacist fills it and the patient takes it, then it is diverted, and so you would refer to that also as a black market.
Q. And it's bought and sold?
A. It's bought and sold.
Q. Do you know what the street value of oxycodone is?
A. Well, the street value of oxycodone runs in most places --
MR. SCHMIDT: Objection, your Honor. Beyond the scope of his expertise.
THE COURT: If you have expertise in knowing the street value, you may answer.
A. As I said earlier, I have been giving talks with DEA all around the country. Part of those talks include local police force talking about the drugs that are available on the streets in those states. We have been to, I'm sorry, I can't remember, 26 states or so. The overwhelming majority of those police officers have stated that oxycodone runs about $1 a milligram for the dosage form.
Q. And so for a 30-milligram pill, what would that equal?
A. It runs around 30 to $40 a tablet, again, depending upon

where in the country you are.
Q. And we were talking earlier about OxyContin. Was OxyContin previously a form of oxycodone that was commonly diverted?
A. OxyContin was diverted almost immediately after it hit the market because of the fact that the people who were abusing it discovered it was easily crushed, it was easy to circumvent the tamper-resistant, supposedly, or the nontamper-resistant dosages form, and they were able to get a much higher dose of oxycodone than the tablet's design intended.
Q. And then --
THE COURT: All right. We have reached our break, and so we'll take a half-an-hour break.
Remember that you are not allowed to discuss the case amongst yourselves or with anyone else. Don't permit anyone to discuss the case in your presence.
(Jury not present)
THE COURT: You may step down.
THE WITNESS: Thank you.
(Recess)
(Continued on next page)

(Trial resumed; jury not present)

THE COURT: May we have the witness back on the stand.

MR. TEHRANI: Just want to raise one quick issue before we brought the witness out and just because we don't want to have -- we want to limit the number of sidebars that we have while the witness is on the stand and while the jury is here.

It appears from the cross-examination of Mr. Brown that Mr. Schmidt intends a very wide-ranging inquiry on topics that as far as I can tell have nothing to do with this case, including internet pharmacy regulations, regulations in Florida that postdated the events in question. There was some lengthy testimony about DEA administrative procedures. None of that is relevant to this case. None of that is relevant to the direct testimony of the witness and, frankly, is wasting not just the witness's time but also the jury's time. So we object to that line of questioning. And we don't want to have sidebars on that so we just wanted to raise it with your Honor.

MR. SCHMIDT: Your Honor, first, I recall that it was the government that first raised the issue of the internet pharmacy because they're the ones that want to put in our client's, or have put in, our client's previous conviction that involved internet pharmacy without really putting any information in the background of what that really meant. So they're the ones who put that into this case. We did not. We

wanted to keep it out of the case. The government put it into the case.

All of the topics that I am raising are topics that have been raised by the government. It goes to both the qualifications of the witness and their knowledge of certain things that they're testifying about.

There are a few other issues that, obviously, I would at this point do not want to alert the government of some of our strategic reasons but, if necessary, I would ask for an ex parte hearing so we can put the additional reasons on.

I do not think I've strayed afield from the areas that the witnesses have testified to.

THE COURT: Well he does make a good point, that you brought out the issue of the internet -- the prior internet misconduct.

MR. TEHRANI: Your Honor, the defendant pled guilty to that. We're not putting in evidence of that. We're not establishing what he did or did not do. He pled guilty to a 846, 841 offense.

We're putting that in because it's relevant to his knowledge with respect to this particular case, his intent with respect to this particular case, and the fact that he is now relying or claiming to the jury to rely on people that were arrested with him in connection with that prior offense.

We are not offering any evidence about internet

pharmacies, about the regulations of internet pharmacies. We now have had testimony from numerous witnesses who frankly were not competent to be testifying about internet pharmacies. To the extent there was a point to be made, I still don't know what it is, but the point has been made. We just don't need to belabor this point with additional witnesses on a subject that is not relevant to the jury.

THE COURT: I think it's fine to make an inquiry as to whether or not internet pharmacies were legal at that time. I don't know how much more is relevant.

MR. SCHMIDT: Your Honor, the simple answer is the government wants to use our client's conviction for participating in an internet pharmacy as some part of their proof and argument and, therefore, we should be allowed to educate the jury what an internet pharmacy consisted of and what it meant so the jury will understand that when they're referring to an internet pharmacy and our client's conviction that they can understand how, if they want to accept the government's interpretation of what it means, or they want to accept our interpretation of what it means. That's all I'm doing.

THE COURT: So it's appropriate to inquire as to whether internet pharmacies are legal per se because just having been involved in the internet pharmacy business does not amount to criminality. Of course your client did plead guilty

to criminal conduct in connection with an internet pharmacy.

MR. SCHMIDT: Your Honor, the problem with the internet pharmacies, some of the internet pharmacies as existed at that time was the nature of how they ran; that there was no doctor/patient contact. That was what the basis of our client's conviction was -- that was the basis of the prosecutions for the internet pharmacy, and that's all it meant. And that's what we're trying to do, is just make it clear to the jury that, indeed, what it meant was that you must have a doctor/client relationship.

THE COURT: So then you can ask a leading question on that issue.

MR. SCHMIDT: I have. On cross-examination.

THE COURT: I think that you can be more economic with your question and I think you can also pose them at a faster pace.

MR. SCHMIDT: Your Honor, the witness that testified prior to this witness we just found out that he was testifying a couple of days ago and a lot of the stuff that is relevant material, even though it was short but it gave me an idea of what he was going to be testifying to, I received last night. So, yes, I'm much less prepared for that last witness than I am for the other witness that I cross-examined and I expect this witness who I will cross-examine.

MR. TEHRANI: We'll leave it at that, your Honor.

Thank you.

THE COURT: Have the jurors come in, please.

WILLIAM WINSLEY, resumed.

(Continued on next page)

(Jury present)

THE COURT: You may be seated.

Remember, sir, that you're still under oath.

MR. TEHRANI: May I inquire?

THE COURT: You may continue the inquiry, yes.

DIRECT EXAMINATION CONTINUED

Q. Now Mr. Winsley, before we broke you were talking a little bit about Oxycontin. Do you remember?

A. Yes.

Q. And you had testified that Oxycontin at one point was a form of oxycodone that was typically diverted?

A. That is correct.

Q. And you also testified that at some point the formulation for Oxycontin changed?

A. Yes.

Q. What was the purpose of that change?

A. In order to deal with the diversion that was occurring, to render the dosage form less liable to crushing and therefore abuse by snorting, injecting, smoking, so forth.

Q. And how did that formulation change affect the prevalence of Oxycontin as a form of oxycodone that was typically diverted?

A. It's gone down because of the fact that the new formulation is harder to abuse. It's still abused, as I said earlier, because people still take it orally. They just take more than

they should. But at the point that it became difficult to abuse, that's when patients started switching or physicians that were writing started switching to oxycodone 30 and 15-milligram; primarily 30 because that's the highest dose.

Q. Do you know what morphine sulfate is?

A. Morphine sulfate is also a Schedule II controlled substance. It's also an opiate. It's also used for pain. In fact, it's one of the oldest pain medications that we have.

Q. What about hydromorphone?

A. Hydromorphone was originally marketed, I believe, by the tradename Dilaudid; also a Schedule II opiate.

And before the oxycodone single, you know, the oxycodone immediate release and Oxycontin came out, Dilaudid or hydromorphone was and still is widely used for pain typically in hospitals.

Q. What about hydrocodone?

A. Hydrocodone is now a Schedule II controlled substance. It's the most widely abused drug still on the street in most areas of the country. It's also the most prescribed prescription drug in the United States. More hydrocodone is prescribed than any blood pressure medication, heart medication, any other drug. Hydrocodone has been for several years the most prescribed prescription drug in the United States.

Q. And all three of those hydrocodone, hydromorphone, morphine

sulfate they are all painkillers?
A. They all are used for the treatment of pain and they all derive from the same source. They are all opiates.
Q. Does that mean that they are perfectly interchangeable?
A. No. They are not perfectly interchangeable. They have different doses, different strengths of action. So one dose is not interchangeable. They have slightly different methods of action that a patient might develop tolerance for one and not the other. So they're not perfectly interchangeable but they're all used for pain and if a physician knows what he or she is doing they can switch from one to the other.
MR. SCHMIDT: Objection, your Honor.
THE COURT: Overruled.
Q. How does a pharmacy order Schedule II controlled substances?
A. For quite some time they've been able to order -- well since the beginning of the controlled substance process they've been able to order on a special government form known as a DEA 222 form to those of us that have had to deal with them. But that's a form that is -- was formulated by DEA and that everybody had to use. Until recently DEA also developed an electronic system by a computer that they call a controlled substance ordering system or CSOS. So now pharmacies and other people that need Schedule IIs can either use the paper form or they can use the computer version.

Q. Referring to the old school paper method of ordering Schedule IIs, who is supposed to sign the DEA 222?
A. Initially it's the person who originally applied for the DEA registration. However, DEA has processes in place to allow that person to grant power of attorney to someone else within the organization in order to sign those. And DEA has specified the form and the wording of that power of attorney.
Q. I'd like to switch gears a little bit and talk to you about pharmacy practice more generally.

According to professional standards, the practice of a pharmacy, what responsibility did a pharmacist have before filling a prescription?
A. A pharmacist has a wide range of responsibilities.

When they're presented with a prescription, the first thing they need to do is to verify that the prescription meets all of the legal requirements: Patient name, drug name, drug strength, quantity, directions for use, in the case of a Schedule II particularly the physician's signature on the piece of paper, and there are other things as well. So they have to determine first of all that it meets all of the legal requirements for a prescription.

Once they do that, they have to review a patient profile that they're required to keep by the state that lists all of the prescriptions that that patient has received from that pharmacy as well as certain pertinent information about

the patient such as disease states, age, maybe weight, of course name and address, that kind of stuff. But they're required to review the prescription against that profile in order to determine that there's not something unreasonable about it and that, in fact, the prescription is appropriate for that particular patient.

Once they do that, then they're required to do what states refer to as a drug utilization review, which means they compare that drug to the other drugs that patient has received, to the patient's disease states that the pharmacist knows or should know about, and they're looking for overdose, underdose; in other words, maybe the physician made an error on the quantity of -- or on the strength, on the directions for use or something.

They're required to look for drug interactions; in other words, whether the drug that's being prescribed will interact with another drug the patient is on and maybe cause the patient harm.

They are required to look for allergies, drug allergies, drug disease state contraindications.

And they're required to look for evidence of or indications of misuse or abuse.

Once -- if they find any of those, or if they find something else on the prescription that we refer to as a red flag which are just some indications that the prescription

might not be all it seems to be on face value, they're required to resolve those problems before they decide to fill it.

Resolving it may mean talking to the patient, may mean talking to the doctor, may mean reviewing the history of either the doctor or the patient. It could be a variety of ways. But they're required to resolve the problems before they agree to fill it.

Once that's done, the prescription can be processed. That task can be done by ancillary personnel. The pharmacist does not have to count to 30 by 5s like you see on TV all the time.

But at the end of the process the pharmacist is accountable for doing the final checks of the finished product and assuming responsibility and liability for that product.

Once that's done, the patient is -- has to be offered counseling by the pharmacist on their drug. That offer can be made by other people. But if the patient needs to talk to the pharmacist about the drug it's a requirement that the pharmacist be the one to go out and do that.

So there's a lot of duties that a pharmacist has to do when presented with a prescription. It's just not simply counting to 30 by 5s.

Q. Now you testified earlier about or used the phrase called corresponding responsibility. Is that what you've just been talking about right now?

A. Yes.
Q. And is one of the things that a pharmacist is supposed to look for in carrying out his or her corresponding responsibility whether there's a valid patient/doctor relationship?
A. Yes. That, of course, is a necessary thing for a prescription to be issued by a physician. There has to be a valid doctor/patient relationship.

So the pharmacist needs to, if the pharmacist is unfamiliar with the doctor or the patient or if there are other problems, the pharmacist needs to ensure that the physician saw the patient and, as I referred to earlier, does all of the indignities that our doctors do to us rather than just write a prescription.
Q. And what are some of the things that a pharmacist might look for to determine whether a valid doctor/patient relationship exists?
A. One would be distance. Most doctor -- most patients go to doctors that are somewhere in a reasonable geographic distance from their home. Now, I will grant you that some patients have to go to specialists in major medical centers so obviously that's an exception. But most patients will not travel that far to go and see their doctor.

The same would hold true for a retail pharmacy standing on the street corner. Most of their patients should

be within a reasonable geographic distance because most patients aren't going to drive past 20 pharmacies to get to one. So distance is one of the things that a pharmacist should look for.

Another that a pharmacist should look for is the dose and quantity of the drugs involved, as to whether or not -- I mentioned before the pharmacist needs to look to see if the prescription is appropriate for the patient. And so if it's for a large quantity of the highest strength of drug, very rarely would patients need that much. And so the pharmacist would need to resolve that issue as well.

It depends upon the situation, what other items the pharmacist might be concerned with, where the pharmacy is located, but in general those are things that the pharmacist would have to look into.

Q. And so one of the things that you were just talking about is the distance between the patient and the pharmacy?

A. Yes.

Q. And is that concern as significant in a mail order pharmacy as opposed to what I'll refer to as a brick and mortar walk-in pharmacy?

A. That's one of the things that mail order specifically needs to keep in mind; that patients still aren't traveling long distances to get to most physicians and so that's something the pharmacist can look at when filling the scrip. I mean nowadays

if we have questions we can get on Google Maps or something and find the distance and if it's a long way or particularly if they're coming from one state to another that's certainly an indication that we may have a problem here.

Q. So I just want to make sure that we're clear on this. There's two different distances at issue. There's distance between the patient and the pharmacy and the distance between the patient and the prescribing physician?

A. That is correct. And for most pharmacies, most retail pharmacies both of them play together because most retail pharmacies, thinking of the CVS, Rite Aid, mom and pop independents, their patients are located within a reasonable geographic area as are most of their prescribers.

Q. So why should a pharmacist be concerned if there's a significant distance between a patient and the prescribing physician?

A. That would be one of those red flags that I mentioned. Red flags are not automatic nos. But they are indications that there may be a problem that needs to be resolved before we go on. So, it's something that the pharmacist should look into to see what the reason is. Again, maybe the physician is in a major medical center and he or she is a specialist. Okay, then that probably resolves the issue.

If the pharmacist finds out that that's not the case, and particularly if the pharmacist finds out or knows that lots

of patients are traveling distances to that physician, then that puts it a little closer to the no-go situation. So it's something that they need to be aware of and look at.

Q. Now you also talked a little bit about counseling previously. What is the purpose of counseling?

A. Counseling was actually a federal requirement years ago and counseling is a chance for the pharmacist to discuss the patient's drug therapy either with that individual prescription or drug therapy in total with the patient. In some states it's mandated. If it's a new prescription, the pharmacist must go out and talk to the patient. In other states it's that the offer must be made and if the patient accepts then the pharmacist goes out. There's also an expectation that in some circumstances the pharmacist will go out and talk to the patient without needing to ask the question.

Q. Is counseling possible if patients are not allowed to visit or contact the pharmacy?

A. Not allowed?

Q. They are not permitted to visit or contact the pharmacy?

A. That would be very difficult for the pharmacist to counsel if they can't talk to the patient.

Q. Is a pharmacist required to call a prescribing physician?

A. Not ordinarily they are not required to call a prescribing physician. They may choose to do so if they have questions or concerns about the prescription. That may be one way to deal

with those questions or concerns.
Q. And does calling a doctor's office to verify a prescription satisfy the pharmacist's obligation?
A. No, not at all.
If a physician writes a scrip that is not legal and the pharmacist calls, it's pretty obvious the physician is not going to say, "You got me, don't fill it." The physician is going to verify that he wrote the scrip and it's for a valid use even if the pharmacist should know better.
So the mere fact that the pharmacist called does not relieve the pharmacist of his or her duty to fulfill their corresponding responsibility requirements.
Q. Is it consistent with a pharmacist's obligations to direct a physician to prescribe a certain number of medications?
A. Nobody should be directing a physician to prescribe. That's the physician's prerogative by law. The physician is the prescriber. And nobody else should be calling and telling the physician: Hey, you need to write for this drug, you need to write for this drug.
There may be some suggestions particularly, as most of us know, the insurance companies don't pay for every drug. The pharmacist may call and say the insurance won't pay for this, they will pay for this, this, or this, which one would you like. But they certainly cannot -- it is not legal for them to call and direct the physician to write a particular

prescription.

Q. Can a pharmacist substitute a different dosage of the same controlled substance without consulting a physician?

A. If you're talking about going from one strength to the other, no. They can make that change after discussing the change with the physician.

In other words, if they want to dispense tablets that are half the strength of that prescribed or tablets that are double the strength and then cut the dose in half, they have to talk to the doctor before they make that change on a controlled substance prescription.

Q. So to use a concrete example, can a pharmacist fill a prescription for 30 pills of eight milligrams of hydromorphone with 60 pills of four milligrams of hydromorphone?

A. Not without talking to the prescriber.

The reason for that being that a lot of patients remember that the doctor said you're going to take one a day or one every four or whatever. Now the pharmacist gives them a prescription that says you're going to take two or vice versa instead of two you're going to take one. The chances of error of patients either taking too little or too much have occurred. In my personal experience we've had several cases of that in Ohio.

So, the pharmacist needs to make sure that the physician is onboard, that the physician's records -- that the

physician knows that that change is occurring. And then the pharmacist, that's one of the indications where counseling would be expected without asking the patient.

Q. Now, we've been talking a little bit about mail order pharmacies as opposed to walk-in brick and mortar pharmacies. How, if at all, do the duties and obligations of a pharmacist differ in a mail order pharmacy as opposed to a brick and mortar pharmacy?

A. Since the federal and state requirements, they're identical. There are no differences. They have the same issues of corresponding responsibility. They have the same -- they need to go through the same process with the prescriptions that I talked about before.

Q. But is it fair to say that in a mail order pharmacy a pharmacist is less likely to actually see a patient?

A. If it's a true mail order pharmacy, which is closed door, no patients coming in, then obviously they're not going to see the patient. There are some mail order pharmacies that also do walk-in and so then there's a possibility. But most mail order pharmacies are closed door. They're not going to see the patient.

Q. So in those circumstances how does a pharmacist carry out his or her corresponding responsibility?

A. Well they still are required to go through all of those issues that we talked about. They still have a profile of meds

that the patient has received. They still are required to do the utilization review that I talked about. They still are required to look for potential issues with the prescriptions and resolve those issues before the prescription is filled.

And then the difference for mail order where the patient is not there is they are required to send a written offer of counseling along with a free-of-charge telephone number and the hours when a pharmacist will be available so that the patient can call and get the counseling or get their questions answered.

Q. Now if an owner of a pharmacy is not a pharmacist what obligations does the owner have?

A. The owner has to have a pharmacist in full and actual charge of the pharmacy. Only a pharmacist can dispense the drugs. If the owner is not a pharmacist, the owner has no rights to be involved in the dispensing process.

Q. What about a nonpharmacist store manager?

A. Same for them. Only a pharmacist can dispense. Only a pharmacist can make the professional judgments involved with the act of dispensing. Nonpharmacists cannot mandate anything relating to those professional judgments. Those are the sole purview of the pharmacist.

Q. Mr. Winsley are you familiar with the term pharmacist in charge or supervising pharmacist?

A. Yes. Pharmacist in charge is a pretty common term that's

used around the country to define the pharmacist most of the time who signed the pharmacy board license application. That pharmacist is the pharmacist that the board expects and holds responsible for the practice of pharmacy within that particular pharmacy itself, making sure that policies and procedures are in place to avoid mistakes, to do things properly and legally. And they're held accountable. Maybe including with the actual pharmacist if there's an error or something. But the pharmacist in charge is held accountable for seeing to it that everything runs properly.

Q. Are you familiar with the term pharmacy technician?

A. Yes. Pharmacy technicians are a group of -- you would call them pharmacy helpers. They are people who are allowed to be in the pharmacy department, to participate in the filling of the prescriptions, but they do the technical work. They can make no professional judgments. That means they can count to, as I say, 30 by 5s. They can pour into the bottle. They can type the label if anybody still does that these days. They can prepare the dose for the pharmacist to do the final check.

But the pharmacist himself or herself has to be, at the end of the line, has to make sure the right drug is in the container, the label is proper, according to the prescription and according to what the patient should get, and that it's ready to go. And then it's the pharmacist who assumes responsibility and liability for the product, not the

technician.
Q. Can a pharmacy technician dispense medication without a pharmacist?
A. No. A pharmacist has to be physically present at all times that drugs are dispensed out of a pharmacy.
Q. So we've been talking a little bit about what you referred to as red flags. Can you describe just generally what you mean by red flags?
A. Those are indications that there may -- keyword being may -- be a problem with the prescription. I already mentioned distance. And I already mentioned the fact that there are exceptions to the distance being a problem, if they're going to a specialist in a big city or whatever.

And other red flags would be early refills or in the case of Schedule IIs filling the scrips before the patient should be nearly out of their old one. And continual early refills is a red flag.

A red flag that needs to be resolved, that's not an indication of a diversion is very late filling of some of the prescription drugs. Because if you're taking blood pressure, for example, you need to take it consistently. So if you're not taking it right that's a red flag that the pharmacist needs to hold up, get ahold of whoever they need to get ahold of.

Another red flag is the doctor's prescribing practices himself or herself. If the doctor consistently writes the same

drugs for pain for all types of people, adults, teenagers, male, female, elderly, the same strength, same quantities, that's an indication of a problem.

The treatment of pain is not a cookbook treatment. We all react differently to pain. Some of us need more treatment. Some of us need less. So if the doctor is consistently writing, particularly for the highest strength of an opiate, the highest strength of some of the other drugs, that's a problem.

If the doctor is writing for combinations of drugs that are known to be not -- no medical value such as an opiate a benzodiazepine like Ativan or Valium and a muscle relaxant like Carisoprodol or Flexeril, that combination of drugs is a problem. And so that's a red flag. Particularly if the doctor is writing it routinely for a lot of patients.

There are a lot of different issues that you can go into with the prescriptions that might raise a pharmacist's concern.

Q. Are there any red flags associated with the quantities of pills on a prescription?

A. Well the quantities -- if you keep in mind that ordinarily opiates are drugs of choice for short term relief of pain, if a doctor consistently writes large quantities for a patient then it's something that the pharmacist would certainly need to look into.

There may be a reason, but for the majority of times it's not indicated -- opiates are not indicated in large quantities of high strengths for patients with chronic pain. There are other methods of treating in addition to drugs.

MR. SCHMIDT: Objection, your Honor.

THE COURT: Overruled.

Q. Were you finished?

A. Yes. I'm finished.

Q. What about multiple patients at the same address receiving the same medication. Is that a red flag?

A. If it's multiple, multiple patients, yes. I mean it might be, you know, two roommates. But even so, as I said before, treatment of pain is an individual thing. If they're both getting the same drugs at the same doses and there's multiple people, three, four, five, that certainly is a major problem that the pharmacist would have to pay a great deal of attention to.

Q. So it's not per se unlawful?

A. I suppose if they lived in a rooming house or a dormitory it might be possible but a normal street address it's highly unusual.

Q. It would be something that a pharmacist would look into?

A. It would be what I would call a red flag which means it would need to be resolved before the pharmacist moved on.

Q. Does the concern -- does it address the concerns to just

send one of the prescriptions to a different address?
A. No. The address needs -- or the prescription needs to be sent to the address of record and they can't be -- it can't be shipped elsewhere.
Q. And you were talking about just a little bit, are you familiar with the term pain clinic?
A. Yes. Pain clinic is -- we use it, refers to legitimate clinics that are run by specialists in pain medicine that deal with patients that have chronic pain. Legitimate pain clinics use not only drugs but a variety of other methods, physical therapy, heat, exercise --
MR. SCHMIDT: Objection, your Honor. May we approach?
THE COURT: All right.
(Continued on next page)

(At the sidebar)

MR. SCHMIDT: Your Honor, he's a pharmacist. Pharmacists have to know some drug interactions. I do not doubt that very much. But he is not qualified for him to testify as to what is appropriate at a pain clinic and what is not appropriate at a pain clinic. He is not a doctor. He is not a physician. I think it's entirely inappropriate.

MR. TEHRANI: Your Honor, I understand that's their defense that a pharmacist has no obligation to know these things or look into these things.

MR. SCHMIDT: That's not what I said.

MR. TEHRANI: He is an executive director of the Board of Pharmacy. He was the president of the National Association of Boards of Pharmacy. As he testified, this is one of the things that a pharmacist is obligated to look into and to satisfy him or herself about before fulfilling a prescription. He's entitled to offer his opinion. He can offer his basis for that opinion, if Mr. Schmidt would like, about pain management, about pain clinics, about pill mills and what types of prescriptions that come to a pharmacy are legitimate or are illegitimate. That is well within his scope of expertise.

THE COURT: So he is now describing what a pain clinic is and it's appropriate for him to describe the various therapies. The application is denied.

(Continued on next page)

(In open court)

MR. TEHRANI: Can we just have read back the last portion of the answer before the objection.

(Record read)

Q. Was there more to that answer that you wanted to provide?

A. I was just going to add electric stimulation is commonly used, conditions like back pain and so forth.

Q. Are you familiar with the term pill mill?

A. Yes. Pill mills are what we use to refer to clinics that call themselves pain management clinics but are not run by a specialist. They are run by a variety of other doctors and, in fact, in many cases they are not owned by doctors. They are owned by other people who hire the doctors to work. These are clinics that specialize primarily in writing prescriptions, large quantities, high doses for people that travel distances in order to get there. These are clinics that have been documented as providing very little of the normal doctor examinations. Basically they are situations where what do you want, how much had money do you have, and the prescription is written.

Q. Now as between legitimate pain clinics and pill mills, would one or the other be more likely to prescribe tamper resistant pain medication?

A. If they were going to prescribe large doses of controlled substances that had or -- not large doses but the higher doses,

particularly higher strength, sorry, of controlled substances, the pain management clinics, the legitimate specialists clinics would be more likely to prescribe the drug that is more difficult to abuse.

Q. Would you expect a doctor at a legitimate pain clinic to only prescribe the same Schedule II controlled substance to every patient?

A. No. That would be opposite to what I've said a couple times here during my testimony in that the treatment of pain is an individualized thing. Some patients can use lower doses of drugs, much lower doses of drugs because the other ancillary methods, the physical therapy, the electric stimulation or whatever is helping them. Some other patients who have a lower pain tolerance may need a little higher dose. But it would be individualized patient, by patient, by patient. It should not be consistently the same drug at the same strength in the same quantities for everybody, male, female, young, old.

(Continued on next page)

Q. Are you familiar with the practice of doctors' involvement in prescription diversion prescribing noncontrolled prescriptions for every controlled prescription?
A. Yes. We've seen that quite a bit where they do that in order to mask the fact that they're writing the prescriptions for patients that are getting it for abuse. Quite frequently, in my experience, those noncontrolled substances that they're writing are not related in any way to the need for the opiate, and in my experience many times when the patients come into the pharmacy, they ask for the controlled substance to be filled but they don't want the other one. That would be another one of the red flags that I talked about for the pharmacist to consider.
Q. Would there be any red flags associated with a patient receiving monthly prescriptions for 30 milligrams of oxycodone at six per day?
A. If that continued very long, certainly that's something that the pharmacist would need to resolve because that would be a very unusual dose. Perhaps over a period of time for a terminally ill cancer patient if they were still able to swallow, perhaps. Although I would expect the prolonged release version to be used so that the patient wouldn't have to swallow so many. But it's unusual for a normal patient in pain to be using the highest strength of an opiate in large quantities for an extended period of time.

Q. What about for a patient with back pain?
A. Back pain. Back pain is one of the disease states, number one, that is very hard to diagnose, but, number two, is treated in a variety of ways, not just with high-dose opiates. All those do is mask the symptoms. They do nothing to help the cause of the pain. So there are other methods, again, as I said before, to help patients with back pain. So if back pain is the diagnosis for every patient coming out of a doctor's office and they're all getting high-dose opiates in large quantities, that is a problem.
Q. Are there any red flags associated with the form of payment?
A. Ordinary pharmacies have a very high percentage of insurance. Most of us in this country have some form of insurance -- not everybody, there are patients who have to pay cash. But when we run across a pharmacy or a physician that's a cash-only business, that tends to cause us to have some concerns and indicates that maybe that particular pharmacist or physician -- pharmacy, I'm sorry, needs to be looked into further because that's very unusual to have a cash-only business in a country where the majority of people have health insurance.
Q. Why would the fact that it is unusual be a red flag of diversion?
A. One of the reasons that's done is because the health

insurance companies themselves do their own utilization review, and they obviously don't want to pay for any more than they have to, for one, but some of them also feel that they need to help with the drug abuse crisis that we have and so they're doing those reviews. They're pushing the issue. They're calling doctors, they're calling pharmacists, and, in fact, they're calling the enforcement agencies when they have indications that there may be a problem with either a doctor or a pharmacy.

MR. TEHRANI: Your Honor, may I have a moment?

(Pause)

No further questions.

THE COURT: Cross-examination.

CROSS-EXAMINATION

BY MR. SCHMIDT:

Q. Is it Mr. Winsley or Dr. Winsley?

A. Mister is fine.

Q. What medical treatment -- what education in medicine have you received?

A. Since the term "medicine" applies to all aspects of treating patients, including physicians, nurses and pharmacists, I have had a great deal of training in the pharmacy end of the medical field. That includes the use of drugs, the drugs themselves, the drugs used in disease states. Of course, I had that education a long time ago. But that's

what pharmacists receive, and in point of fact pharmacists received --

THE COURT: What do you mean by "drugs used in disease states"?

THE WITNESS: For example, if you come down -- I'm sorry. If a patient comes down with pneumonia, there are certain drugs, antibiotics, and other drugs that would be used depending upon where it is. If a person has pain, there are certain drugs that are used for pain and you wouldn't use an antibiotic, for example, for pain. So relating disease state, what's wrong with the patient. They have high blood pressure, so there are medications used for blood pressure. So that's what I mean about drug disease state.

And in point of fact, pharmacists have more training in the use of drugs and disease states than do physicians, nurses, dentists, any of the others. When they come out of school, pharmacists have more training in the drugs themselves.

BY MR. SCHMIDT:

Q. It's important for pharmacists to have training because they are the professionals relating to the filling prescriptions of all sorts of drugs, right?

A. Yes.

Q. And there is quite a bit of responsibility placed on the pharmacist to make sure that the drugs that they're prescribing is helpful to the patient and not harmful for the patient, is

that right?
A. That is correct.
Q. You are from Ohio. Does Ohio have continuing pharmacy education requirements?
A. We have a higher requirement than any other state that I know of.
Q. So is the answer yes?
A. The answer -- yes.
Q. And how frequent are -- what must a pharmacist do in Ohio to maintain his pharmacist license?
A. They have to do their continuing education, which for us is 20 hours a year, three -- well, one of which per year. We report continuing education every three years, a third, a third, a third every year.
THE COURT: What do you mean by the term "continuing education"?
THE WITNESS: That's ongoing education. Continuing education is ongoing education that a licensed individual, be it a physician, pharmacist, nurse, dentist, is required to do in order to maintain their competence in their particular field. So it is not that they graduate and they're done, they have to continue to try to keep up with the changes. The changes in the medical field are occurring rapidly, and so they have to continue to go to classes, lectures, those types of things in order to keep up.

Those are some of the lectures that I talked about me doing with DEA going around the country. The pharmacists get credit for attending those classes that we put on, and that's what most of my talks around the State of Ohio and other states and nationally have been so that pharmacists or another professional can get education credits. That's what continuing education is.

BY MR. SCHMIDT:

Q. So how many credit hours either per year or every two years must a pharmacist have to maintain his license -- his or her license?

A. In Ohio it is 60 hours every three years, three hours of which have to be in Board of Pharmacy-approved law classes.

Q. What about the State of New Jersey?

A. I believe New Jersey is 30 hours every two years, if I remember correctly.

Q. Do you know about the State of Florida?

A. No.

Q. Do you know if they have a CLE requirement or not?

A. No -- well, I don't know about "CLE." They do have pharmacy continuing education.

Q. Excuse me. You are an attorney. I meant for pharmacy.

Do they have --

A. Yes.

Q. -- continuing pharmacy education?

A. Yes.
Q. But you are not familiar with the amount, is that rights?
A. No. I don't know whether it is 15 hours a year. Some states are 15 every year. Some are 30 every two years. I only know of Ohio being 60 every three being higher than any of the other states that I know of.
Q. If you can answer the question shorter, with a "yes" or "no," please do.
What about the continuing educational requirements for a nonpharmacist owner of a pharmacy, how many hours do they take a year?
A. None.
Q. That is in Ohio, right?
A. I don't know of any state that has requirements for that.
Q. So it is fair to say that the nonowner pharmacy -- the nonpharmacist owner or nonpharmacist manager of a drug store must rely on his or her pharmacist to be up to date in all of the rules and requirements, is that correct?
A. Yes. That's why the pharmacist in charge is mandated.
Q. You said when you grew up you worked in your parents' pharmacy?
A. I did.
Q. Nowadays there is not that many of them, especially in larger cities, is that right?
A. That is correct.

Q. Now, I don't know if it is in your knowledge or not, but if it is in your knowledge, the manager of a CVS store or a Walgreen's or a Rite Aid, they are not going to be a pharmacist, are they?
A. Not usually.
Q. They will be -- you go into one of those chain stores, you have a sign, usually in the back of the pharmacy, where it says "Pharmacist in charge," doesn't it?
A. Not -- I mean any pharmacy I have been in, it doesn't say "pharmacist in charge." Many of them have the wall certificates of the pharmacists hanging there with their names on them that were given to them when they passed their initial examination. But I don't know a pharmacist -- some individual stores may say pharmacy manager or pharmacist in charge but it's not a mandate that I know of.
Q. Now, so for the many years, your years involving -- being involved in the Ohio State Board of Pharmacy, you in many ways were a law enforcement officer, is that right?
A. Without arrest powers, yes. The Board was a law enforcement agency.
Q. Now, you testified, I think, in federal court on a few occasions?
A. Yes. Two.
Q. And who did you testify on behalf of?
A. One was the State of Ohio, the first one, and the second

one was the Philadelphia U.S. Attorney's Office.
Q. Are you aware of the ongoing discussion in the country about generally the treatment of pain by opioids?
A. Yes, I'm aware of the ongoing discussion.
Q. And you do understand that part of that discussion is indeed pain experts who are talking about that pain is not being managed aggressively enough, is that right?
A. Not since about 2000 -- or, yes, 2012, that's not correct.
Q. Are you aware of the University of Wisconsin School of Medicine Public Health?
A. I know that they have one.
Q. Are you aware of their involvement in the discussion of whether or not pain is treated sufficiently aggressively?
A. I know that they were early on. I have not seen anything from them recently.
Q. Well, would it be fair to say that as late as 2013 -- 2014, they published a quite substantial document that was entitled "Achieving Balance in Federal and State Pain Policy, A Guide to Evaluation"?
A. I can't say whether they did or not. I haven't seen it. However, that doesn't correlate with your previous question about pain not being adequately controlled.
Q. I appreciate your full answer, but, please, just answer my question and the government will have an opportunity to ask you additional questions if you are not satisfied with the answer

to my question. OK?
A. I understand.
THE COURT: In other words, answer the question without volunteering additional information.
THE WITNESS: OK. I will do my best.
BY MR. SCHMIDT:
Q. Are you aware of them publishing in 2014 -- 2013, "Evaluation of Achieving Balance in Federal and State Pain Policy"?
A. No.
MR. SCHMIDT: May I approach the witness?
THE COURT: You may.
Q. Have you ever seen that document?
A. No, I have not.
Q. Have you been following the discussion and articles that are coming out from the University of Wisconsin School of Medicine and Public Health in the last three years?
A. I have not been following that, no.
Q. So you are willing to tell us what you think is a legitimate pain clinic without reviewing documents from -- withdrawn.
Isn't it a fact that the University of Wisconsin School of Medicine and Public Health has published at times joint statements with the Drug Enforcement Administration?
A. That's a possibility.

Q. You don't know?
A. Not as it relates to the University of Wisconsin. I'm familiar with early University of Wisconsin publications but not in the timeframe you've asked about.
Q. OK. Let's not do the timeframes I've asked about. Let's start from the year 2000. Did they publish the statements and articles together with the DEA?
A. I believe they did, yes.
Q. Do you recall them?
A. Not with DEA, no.
Q. Do you recall a 2004 joint statement from 21 health organizations and the Drug Enforcement Administration called "Promoting Pain Relief and Preventing Abuse of Pain Medication, A Critical Balancing Act"?
A. I'm aware that something like that was put out. I read it back then. That was a long time ago, so I don't remember all of the particulars.
Q. So is it your testimony now that there was a dispute about what was necessary in pain management back in the early 2000s but that is no longer an issue now?
A. What I'm saying is that a lot of the people who were addressing that concern and going around the country preaching it have since recanted what they did. Specifically one Russell Portenoy in the Wall Street Journal in 2012, who said that he and other pain management specialists erred in preaching the

doses and minimizing the side effects. I'm also aware that Congress was investigating a lot of those groups, many of whom went out of business after they found out that they were funded solely by the drug companies. So that's why I said after 2012 that little -- that pressure has kind of died off of it being undertreated. Now, in fact, we have an epidemic due to overtreatment.

Q. Thank you, Mr. Winsley.

Were you told when you were testifying to try to get as much information out as you could to every question --

MR. TEHRANI: Objection, your Honor.

Q. -- or is that on your own that you are doing that?

MR. TEHRANI: Objection again, your Honor.

THE COURT: Once again, I want you to stick to the question that has been posed without offering or elaborating.

THE WITNESS: Yes, ma'am.

BY MR. SCHMIDT:

Q. So is it your testimony now that a pain clinic that primarily provides opioids for its patients is not a legitimate pain clinic?

A. Usually, yes.

Q. You used the word "usually." Now, how many actual -- let's say in Ohio. How many pain clinics in Ohio have you actually gone to in the last ten years prior to retirement?

A. I don't have an exact number but I have been to several.

Q. And did you examine their patient records?
A. No.
Q. Did you have a doctor examine the patient records?
A. The doctor was familiar with the patient records.
Q. Did you have a doctor other than the doctor at the pain clinic examine the patient records?
A. When it was a pain clinic that we were charging, yes.
Q. So you wanted to have a doctor's opinion as to whether the doctor thought that these records reflected the need for pain medication, is that right?
A. That was a requirement for a criminal case.
Q. It wasn't a pharmacist that did it?
A. Well, there were pharmacists involved, too.
Q. It wasn't a pharmacist that made that determination, was it; it was a doctor, because it was necessary, right?
MR. TEHRANI: Objection, your Honor. I'm not sure what "that determination" is.
THE COURT: Overruled.
You may answer.
A. Can you run that past me again please, then?
Q. You required -- when you were the head, Director of the Ohio Board of Pharmacy that was law enforcement for the violation of the drug laws in Ohio, before you brought a case, you had a doctor examine the patient records of a pain clinic doctor, is that right?

A. Yes.
Q. Did you examine any pain records -- excuse me. Did you examine any medical records in this case?
A. No.
Q. Now, there has been some very recent changes in the chemical makeup of some of the oxycodone pills, is that right?
A. Very recent? No.
Q. Let's start. In 2013, the Federal Drug Administration came out with guidance for the drug industry in order for them to come up with extended-release oxycodone that limited the euphoric effects of the oxycodone if crushed and used, is that right?
A. Not that I know of. It was -- the formulation was changed before 2013.
Q. When are you aware of that it was changed before 2013?
A. I'm sorry. What am I aware?
Q. When do you think the first time that the formulation of oxycodone was changed for extended release to prevent the euphoric effects of crushing and using those pills?
A. I don't know exactly when it was. It is my belief that it happened before I retired.
Q. What was the name of the drug?
A. It was OxyContin.
Q. Well, because the company came out with something pretty special. Didn't they have a name?

A. OxyContin was the name. Oxycodone is the generic name.
Q. The new extended release that was going to make it less useful to divert it to crush it and get a high, right, did they just put it out as a generic name?
A. No, I don't recall the name.
Q. Well, wasn't that some substantial change?
A. It may have been.
Q. But you don't remember the name?
A. I don't remember the name.
Q. Do you know the name of the manufacturer?
A. No, if I don't remember the name.
Q. In fact, as late as 2013, the National Institute of Health was giving warnings about crushing extended release oxycodone and using it that way, isn't that right?
A. I believe you are correct.
Q. Because they didn't want people to use it in 2013 because it still would give a euphoric high and was dangerous, isn't that right?
A. Yes.
Q. So if a prescription is written in 2011 or 2012, there was extended-release oxycodone that was available that you could crush and by crushing it you could still get the euphoric high from it as you could for a nonextended release, isn't that right?
A. I don't believe so but I retired in 2011 and if something

came out after that, I may not have seen it.
Q. So you stopped -- OK. When you were at the Ohio Board of Pharmacy, as the head of it, did you keep up to date with all of the new controlled substances that were coming out?
A. I tried.
Q. And then once you retired you haven't really kept up nearly as well, have you?
A. Not as well.
Q. But you've kept up enough to get paid to go around the country and give lectures on diversion, is that right?
A. And on corresponding responsibility, yes.
Q. And you've gone around at times with representatives of the Drug Enforcement Administration, is that right?
A. That is correct.
Q. And have you been paid for any of these lectures by the Drug Enforcement Administration?
A. They cover my travel expenses and that's it. I have not been paid for my time.
Q. Now, you told us about how a legitimate pain clinic would be a clinic that had a -- what's the language -- run by specialists in pain management, is that right?
A. Yes.
Q. Now, are you aware of the Florida laws relating to pain management?
A. Yes.

Q. And that is because fairly recently you had a case where you testified and you needed to know the Florida law?
A. No. The Florida laws originally were passed before I retired, and Florida law was then used as a suggested language in the State of Ohio, which we changed and we got our own version passed in Ohio in the spring of 2011.
Q. So before you retired at the end of 2011, was that?
A. I retired, yes, at the end of 2011.
Q. The Florida law was that a pain clinic had to be run by a person who took some type of courses in pain management, is that right?
A. I believe it is.
Q. And they had to be registered as such?
A. Yes.
Q. And there were certain penalties if it wasn't done that way, is that right?
A. Yes.
Q. That included either fines or loss of license or even prosecution?
A. I believe all three.
Q. When they passed those laws in relation to pain clinics, do you know if Florida made any changes of the laws in relation to pharmacies?
A. Not that I am aware.
Q. You've said that pharmacists have a corresponding duty, is

that correct?
A. Responsibility, yes.
Q. Responsibility, OK.
Now, when you say "corresponding," that means first you look at the doctor, right, and then he had a similar responsibility; would that be fair to say?
I will withdraw that question.
A. Yeah.
Q. I will withdraw that question.
So the doctor's responsibility for writing a prescription, especially a controlled-substance prescription, in Florida required a physical examination, is that right?
A. Yes.
Q. It requires a determination that the best treatment for that particular patient is what the doctor recommends, is that right?
A. Yes.
Q. And the doctor must keep the records of his treatment of his patient, is that right?
A. Yes.
Q. And those records are available to the state boards, is that right, for examination if they're inspecting the pain clinic?
A. Only those that have the right to those patient-protected records.

Q. The confidentiality?
A. Right.
Q. But for pain clinics, right, for inspections by Florida, there was the right for the inspectors to review those records, isn't that right?
A. Yes, the records they needed.
Q. Now, to issue a prescription of a controlled substance, there are basically two general requirements -- one, that it's medically necessary and the second, that it is in furtherance of a professional practice, is that right?
A. No. There's a third one.
Q. What is the third?
A. It has to be a licensed prescriber, a practitioner.
Q. Now, who defines what a -- withdrawn. How is -- withdrawn.
Who defines what "medically necessary" is, the DEA or the state board?
A. Medically necessary?
Q. Yes.
A. Would be -- the ultimate determination would be the state board of medicine in that particular state.
Q. And do you know the definition of what is medically necessary in Florida, or was necessary in Florida between 2011 and 2013?
A. No.
Q. The other part of that is -- withdrawn.

One is there has to be a licensed professional; that's basically self-defined, right?
A. A prescriber.
Q. Yes.
A. Yes.
Q. And the other one, that it has to be in the professional practice of the physician, is that right?
A. Well, the usual course of professional practice of the prescriber.
Q. And who defines the usual course of the professional practice of the prescriber in Florida, the Florida Board or the DEA?
A. No. The State Legislature through the laws.
Q. And what indeed is the definition of that in Florida?
A. The definition of?
Q. The usual course of a professional practice of the prescriber.
A. The usual course of professional practice is the practice limits that are set by the state legislature and law.
Q. And what are those in the State of Florida?
A. For a physician, it would be treating humans.
Q. Excuse me?
A. For a physician, it would be treating humans.
Q. OK. And is it further defined?
A. I don't know that Florida goes any further or whether they

do or not.
Q. Does the DEA define that, that expression?
A. No. They defer to the state standard of practice that's set by the state legislature.
Q. What is the -- what are the -- how are the obligations of a pharmacist defined in the State of Florida?
A. The obligations?
Q. Yes, before they fill a controlled substance prescription.
A. Well, we went through the whole issue of corresponding responsibility on direct, and so those obligations are there. They also have to determine that the physician is authorized to write that prescription.
Q. So -- but the corresponding responsibility is to determine that the prescription was written by a licensed professional, that it was medically necessary in the normal course of his or her professional practice, correct?
A. Yes. Legitimate medical purpose rather than medically necessary, but yes.
Q. Legitimate medical purpose --
A. Right.
Q. -- for the usual professional practice of the prescriber, is that right? Did I say it right?
A. Close.
Q. And where is that defined?
A. There is a regulation on corresponding responsibility in

both the Code of Federal Regulations, Title 21 Section 1306.04, which applies nationwide.
Q. And what are those requirements?
A. That a prescription must be issued for a legitimate medical purpose by a prescriber or practitioner in the usual course of professional practice.
Q. Where is that further defined in the DEA regulations or the rules, federal rules?
A. It is -- that is the federal regulation.
Q. So it is not further defined; is that what you're saying?
A. Well, the rule goes on. That's only the first sentence in that -- in paragraph A of that rule.
Q. Is "legitimate medical purpose" defined in the rule?
A. No.
Q. Is "in the usual course of professional practice" defined in the rules?
A. Not in the federal rule.
Q. Is it defined in the State of Florida?
A. Yes. We've already said that's defined by the State legislature. They set up the standards for each profession.
Q. And the most recent information was passed around the time that you retired, is that right?
A. That I'm familiar with, yes.
Q. Do you know the corresponding responsibility of a pharmacist in New Jersey?

A. Yes. I read their -- I read New Jersey's law on corresponding responsibility. It basically mimics under federal language.
Q. Now, what is the responsibility of the nonpharmacist owner in New Jersey in relation to filling controlled substance prescriptions?
A. The obligation of the nonpharmacist owner in New Jersey --
Q. Yes.
A. -- is that they have to hire a pharmacist to be in full and actual charge, and New Jersey law says that both the pharmacist and the owner are subject to any violations of the pharmacy practice laws.
Q. When New Jersey finds that a pharmacist -- withdrawn.
If New Jersey finds that a pharmacist did not follow all of the requirements that he is supposed to, the pharmacist faces what kind of punishment in the State of New Jersey?
A. Potentially two different kinds of punishment. One would be administrative in front of the Board of Pharmacy and one potentially could be criminal.
Q. That would depend, obviously, on the violations, is that right?
A. That is correct.
Q. You seem to be very conversant about the diversion of a controlled substance, isn't that right?
A. Yes.

Q. Now, are you also aware of the repeated regular complaints coming out of chronic pain sufferers of the difficulty in obtaining oxycodone?
A. I am familiar with the media reports.
Q. The media reports began when the DEA was cracking down on what they said was illegitimate pain clinics, is that right?
A. No.
Q. It started before that?
A. Yes.
Q. Are you aware of CVS and Walgreens having conflicts with the Drug Enforcement Administration in 2011, in 2012?
A. Oh, yes, I am.
Q. And that's because the pharmacists -- excuse me. It started I think in 2009, maybe. Do you remember when exactly it started?
A. No.
Q. OK. That's because the pharmacists in those stores were not doing what they were supposed to do in checking the prescriptions of people coming in with oxycodone prescriptions, isn't that right?
A. Yes. For the pharmacies, that was the situation.
Q. And, in fact, Walgreen's paid an enormous fine to settle, is that right?
A. Yes. Walgreen's paid a huge fine.
Q. So did CVS, is that right?

A. It runs in my mind they got their store's license or DEA registrations revoked. I could be --
Q. I am going to get to that.
A. OK. Sorry.
Q. They had to pay a fine as well?
A. Yes.
Q. And they had some stores revoke their licenses, is that correct?
A. Their registration with DEA, yes.
Q. Which meant they could not fill controlled substances, Schedule I through V, prescriptions for a period of time, is that right?
A. Schedule II through V.
Q. Schedule II through V?
A. Right.
Q. Marijuana hasn't moved yet from I to II?
A. No.
Q. And that basically put those pharmacies out of business.
A. It could have.
Q. How many pharmacies are you familiar, in the State of Ohio when you were running the Board, continued to function when they did not have the ability to fill prescriptions of controlled substances?
A. I don't know that we had any that didn't have the ability that we left them with a license to do anything. So in that

answer, I don't know of any because we revoked them as well.
Q. It could be -- they could, you know, just fill prescriptions for, I guess, amoxicillin and things like that that would not be a financially rewarding business, would it?
A. No, that's incorrect.
Q. Now, as a result of the finding, as a result of the agreements and the fines, you are aware that Walgreens and CVS stopped filling lots of prescriptions that they used to fill, is that right?
A. I'm not aware that they stopped filling.
Q. I will rephrase, then.
Now, one of the things that you talked about as a red flag -- withdrawn.
One of the things you talked about that as a pharmacist you do is you take a look at the past prescriptions that were filled by a patient, is that right?
A. Yes.
Q. Now, for a new patient, that's not particularly practical, is it?
A. No. For a new patient, obviously there is no history.
Q. So for a mail-order pharmacy receiving a new prescription, that's not something that they can really do, can they?
A. Well, that's not quite correct. I mean, they can't look at the prescriptions that they have filled.
Q. Well, that's the question.

A. OK. They can't do that part of it, no.

Q. Now, in fact, there was -- if a patient -- withdrawn.

Did you hear of pharmacies running out of oxycodone before their next shipment was expected from their wholesaler?

A. Yes.

(Continued on next page)

Q. And did you hear about wholesalers sending the order to pharmacies including everything but the Schedule II controlled substances?
A. Not specifically. I'm aware of problems.
Q. Now are you familiar the National Community Pharmacist Association?
A. Yes.
Q. How come you're familiar with that organization?
A. They're the association of primarily the independent pharmacists and pharmacies around the United States. And I've had numerous dealings with them both with the Board of Pharmacy and when I was in the sequence through NABP.
Q. They are a legitimate organization?
A. Yes.
Q. Legitimate pharmacists?
A. Yes. They're an organization that represents retail pharmacy.
Q. Well are you aware that they did a study in January -- excuse me, December 2013 about the problem of their pharmacists, pharmacies receiving controlled substances from their wholesalers?
A. I am not aware of their study. I am aware of the problem.
Q. In being aware of the problem, are you aware that approximately 75 percent of the members of the National Community Pharmacists Association experienced three or more

delays of issues caused by stopped shipments of the controlled substances over that past 18 months?

MR. TEHRANI: Objection, your Honor. He testified he's not familiar with the study.

THE COURT: Sustained.

Q. Would a study -- how would that -- if a patient is coming at the end of the month trying to get their pain meds and their pharmacy says I'm sorry I don't have any left, that patient has to choose between doing without or going to another pharmacy; is that correct?

A. Unless the pharmacy can obtain some quickly. Yes.

Q. And in Florida as a result of the DEA crackdown pharmacists were reluctant to fill prescriptions of people who they've never seen before appear at their pharmacy; isn't that right?

A. Not completely.

Q. Partly right?

A. Partly right.

Q. There are some people they would accept and some they wouldn't?

A. Some pharmacists would accept people and some pharmacists would not.

Q. Are you aware of the agent in charge of -- the DEA agent in charge of South Florida appearing at a Board of Pharmacy meeting down there and urging -- begging pharmacists to fill prescriptions for oxycodone for patients who needed it?

A. No. I am not aware that that happened.
Q. Do you think you might have been aware of that when you were still with the Ohio Board of Pharmacy?
A. Probably not.
Q. Is that because that was in Florida?
A. No.
Q. You don't look at the internet?
A. We had the same problems in Ohio with some individual pharmacists.
Q. The individual pharmacists were overly concerned with what would happen to them if they filled all these prescriptions; is that right?
A. Overly concerned, yes.
Q. Overly because you didn't think that their concerns with what the DEA would do was a real concern; is that right?
A. That's what we told our pharmacists, yes.
Q. You testified that opioids should be used for treatment only for the short term.
A. I said indicated for the use, for the short term use.
Q. Is that something different than should?
A. Probably not different than should.
Q. Isn't it a fact that many, many pain specialists have determined that for some of their patients that opioid medication is what works and allows these people to live a fairly normal life? Is that right?

A. Some pain specialists in limited patients I would agree with.
Q. So you say limited. So what percentage of the people with severe and chronic pain, what percentage of that are the ones where oxycodone is the only thing that's really going to make it work?
A. I don't have a percentage.
Q. You have no idea, in other words?
A. I do know what pain specialists have said and opiates are not the method of choice.
Q. And was the one who changed his mind?
A. I beg your pardon.
Q. You have no training -- withdrawn.
Have you ever examined a patient who was in pain?
MR. TEHRANI: Objection, your Honor. We've covered this.
THE COURT: Sustained.
Q. Now, isn't it a fact that oxycodone is used in treatment from moderate to severe pain?
A. It's indicated that way in the package insert, the FDA approved.
Q. Do you agree with that?
A. Not completely, but pretty much. Usually more severe. There are other products.
Q. So you disagree with, to some extent, the FDA approval?

A. Let me go back. You were talking oxycodone by itself or Oxycontin? Is that the question that you asked me originally?
Q. The question I asked you originally was oxycodone wasn't just used for severe pain, it's also used for moderate pain?
A. Okay. I apologize. In combination, such as the Percocet product, in smaller doses, yes, it's used for moderate pain.
Q. So you're saying that oxycodone without the other drugs that are done in combination shouldn't be used for moderate pain. Is that your statement?
A. Yes.
Q. Do you have respect for the Mayo Clinic? Are they a pill mill?
A. Not as far as I know.
Q. And have you ever looked at their website to see what they recommend oxycodone -- opioids for moderate to severe pain?
A. No. I have not looked at that website.
Q. How about the National Institute of Health? Have you looked at their website as to the use of oxycodone for moderate to severe pain?
A. Not for that particular purpose.
Q. Whose website have you looked at or have you looked at any website in making your determination that oxycodone shouldn't be used for moderate pain?
A. I'm answering the question as a pharmacist who has been involved with the pain management crisis for years.

Q. The pharmacist is asking you?
A. No. I am answering as a pharmacist.
I will admit that the package inserts include moderate which is where all of those websites got their -- got their statements.
Q. And those inserts are approved by the FDA; is that right?
A. Yes.
Q. And it's legal?
A. Oh, yes.
Q. And doctors who prescribe oxycodone for moderate pain is legal?
A. It is legal.
Q. And pharmacists who fill prescriptions under the proper circumstances of oxycodone for moderate pain is legal? Is that correct?
A. Under the proper circumstances.
Q. Have you reviewed the studies that talk about the risks of dependency and addiction for oxycodone?
A. I've reviewed some.
Q. Could you tell us which studies you've reviewed?
A. Not by name.
Q. When was the last time you reviewed a study?
A. Just recently. Not a study. It's also in the package insert approved by the FDA.
Q. So let's go back to studies. What's the difference between

a packet insert and a study?
A. Well a study is something that's done independently. May or not be published in a peer review journal.
The package insert is a compilation of the best information available at the time to the FDA and to the manufacturer.
Q. A study is when a certain number, a valid number of patients are given some type of medication and they check on what the purpose of the study and come out with a result; is that right?
A. That's one kind of a study, yes.
Q. When we're talking about pain medication, that's the kind of studies that are done, to see if they're safe, to see if they're addictive, to see what the side effects can be, right? That's a study, right?
A. That's a study. There are multiple studies, multiple types of studies.
Q. But a study is basically where they actually do research on people who actually use the substance, right?
A. Yes.
Q. Have you read any studies in the last ten years on the use of oxycodone to treat pain management?
A. Yes.
Q. Could you tell me some that you've read?
A. No.

Q. Could you tell me the last study that you read; not insert, study?
A. It would have been before I retired in 2011.
Q. Now, dependency and addiction are two different terms, aren't they? Not just in the words used but the meaning of them; isn't that right?
A. Yes.
Q. Addiction means you have a physical reaction when you stop using something; is that right?
A. (No response).
Q. Or it could be a psychological also, I guess. Some kind of reaction when you stop using it; is that right?
A. That's part of the definition.
Q. Why don't you give us a complete definition?
A. Addiction is taken to mean also that the patient is to the point where they will do other things in order to maintain their drug. So it's not just that they have withdrawal but an addiction means that they're willing to go outside the law in order to maintain their drug therapy or their drug intake. That's usually the accepted definition of addiction that's been widely accepted around the country.
Q. And dependence is what?
A. Well dependence means you still have a reaction if you suddenly stop the drug. Your body has gotten used to having that level. You're not yet to the point that you're going out

on the street corner and buying drugs or going to your neighbor's house and getting into the medicine cabinet but you still need the drug otherwise you're going to have a physical reaction.

Q. Now, when they do studies about the effect on use of opioids one of the important things that they consider is what happens to patients with a history of drug abuse and what happens to patients who don't have a history of drug abuse; is that right?

A. Well really it depends on who they are and how the study is done. But that's one of the things that some people have looked at, yes.

Q. Are you familiar with the studies that show that, for example, out of twelve thousand patients treated with opioids who did not have a history of substance abuse only four patients developed a dependence on the medication?

A. No. I'm not familiar with that study.

MR. TEHRANI: Your Honor, may we be heard on this?

(Continued on next page)

(At the sidebar)

MR. TEHRANI: Your Honor, we haven't been objecting but this is exactly what we were talking about beforehand, about some wide-ranging inquiry about a host of topics that are not typically relevant.

I also note on this last topic I find it curious that Mr. Schmidt wants to go into this topic given that they specifically objected to the testimony of Mr. Bishop and plenty of other evidence that we can present about the drug -- the criminal histories of Plainfield's patients, that they did not want us to present before the jury, that we did not present before the jury, and now he's going into some study -- I don't even know where the study is from, maybe we can be informed of where the study is from -- but some study about the difference between addiction and dependence and whether it correlates to prior drug addiction or prior criminal history or whatever it is that Mr. Schmidt is going into. But this so far afield of anything that is relevant to this case.

THE COURT: I agree. You have to move on.

MR. SCHMIDT: If I may, your Honor. I objected to what I believed was this witness giving testimony about his opinion that I thought that was reserved for physicians. He was able to testify to opinions and conclusions of what I consider of something that would be in the purview of physicians. That's why I'm going into these areas. That's why

I'm questioning on that. Because I don't think he has a valid basis of having these -- a valid expert basis of having these opinions.

THE COURT: So I disagree with you and I already told you that. And I want you to move on.

MR. SCHMIDT: Okay.

(Continued on next page)

(In open court)

Q. Could you tell us what the word tolerance means?

A. Tolerance means that the patient needs more of a drug to achieve the same effect.

Q. So for a person who has chronic severe pain -- withdrawn.

You told us that 30 milligrams of oxycodone was the largest single dose -- dosage amount other than for extended release?

A. No. Immediate release.

Q. I said other than extended release.

A. I'm sorry. I didn't hear the "other than." Yes.

Q. So, a patient who has been in severe pain over the course of many years and finds that oxycodone allows them to live a relatively normal life can develop tolerance for the opioid; is that right?

A. Yes.

Q. But that patient could not get more than 30 milligrams for immediate release; is that correct?

A. Well in one tablet.

Q. That's right. In one tablet.

So that might mean that the person who has been suffering for a long time -- withdrawn.

You testified that for the immediate release oxycodone that they are usually taken every four to six hours?

A. That's the indication.

Q. So, a person who has severe pain for a long time who is developing some tolerance, right, is more likely to take it every four than six -- rephrase that question.

It would likely mean that the person who has been -- the maximum that a doctor should prescribe pursuant to the information within the insert for oxycodone 30 is one tablet every four hours; is that right?

A. I believe that's in the package insert.

Q. So a patient who basically needs oxycodone because of their severe pain finds that that's what works is not going to receive or should not receive more than four -- more than four hours -- withdrawn.

A person in severe pain, chronic pain should not receive from the doctor more than 120 -- I apologize.

The maximum dosage should be six pills a day of 30 oxycodone; is that right, pursuant to the insert?

A. Well if you go by the insert strictly, then if I remember correctly that it is one every four; then, yes, it would be six a day.

Q. But it means that somebody who just started having severe pain shouldn't be starting out like that; is that right?

A. Yes.

Q. They should be starting out lower doses as much as possible; is that right?

A. Yes.

Q. As time goes by they may have to have increased doses; is that right?
A. Until they achieve effect.
Q. When you're talking about chronic severe pain you're talking about pain that lasts not for a short specific period of time but is ongoing, right?
A. Yes. Or at least for a prolonged period.
Q. And for the difference between -- withdrawn.

The advantage of the immediate release is that if you go through a period of time where you really don't have severe pain you don't need to take it, right?
A. That would apply to both.
Q. But immediate release is taken as needed; is that right?
A. Not always.
Q. Could be taken regularly as well?
A. Quite frequently it is.

(Pause)

THE COURT: Mr. Schmidt.

MR. SCHMIDT: Yes, your Honor.

THE COURT: Would you please pose a question.

Q. You told us about red flags. And you said that red flags must be resolved. Do you remember that?
A. Yes.
Q. Now could you tell me where in the instructions to pharmacists in New Jersey would you find that red flags must be

resolved?
A. In the corresponding responsibility rule.
Q. Does the corresponding responsibility rule state that red flags must be resolved?
A. No. It says legitimate medical purpose.
Q. And so the red flag idea is an interpretation of the corresponding responsibility; is that right?
A. Yes.
Q. And, in fact, you lecture on red flags, don't you?
A. Yes.
Q. And the DEA frequently talks about red flags, don't they?
A. Yes.
Q. But in the laws of the State of New Jersey, the law of the United States, the Controlled Substance Act, there is nothing in there that actually say anything about red flags; is that right?
A. That is correct.
Q. But if you're a pharmacist who is taking their CLE -- their continued pharmacy education courses, reading the journals, professional newsletters, that they are likely to come up with the phrase red flag?
A. Yes. It's been widely disseminated.
Q. And the responsibility of taking the continuing pharmacy education courses and keeping up with the newsletters and the changes of law is on the pharmacist; is that right?

A. Yes.
Q. Is it fair to say that the addition or subtraction of red flags can occur any time that either the DEA or someone like you at the Ohio Board of Pharmacy thinks that oh, this is something else that a pharmacist should consider; is that right?
A. Well not just limited to those sources.
Q. Well if the DEA thinks that Oh, we have another example that might cause problems in diversion, they notify, I would assume, the boards of pharmacy throughout the country?
A. Yes. As well as other organizations like NABP.
Q. And you -- when you were the head of the Board of Pharmacy, then you would send something out to the licensed pharmacists in the state?
A. If it was a potential problem I'd probably put it in the newsletter.
Q. It goes to the pharmacists?
A. And other people, yes.
Q. Now, you were asked questions about in your experience you have found that when doctors write prescriptions for noncontrolled substances they usually are not related to the needs of the patient?
MR. TEHRANI: Your Honor, that question mischaracterizes the testimony.
THE COURT: Sustained.

MR. SCHMIDT: Characterize it correctly, please. Did you say something like that?

THE COURT: Ask him a question.

MR. SCHMIDT: Excuse me?

THE COURT: Counsel, ask him a question. I sustained the objection.

Q. Did you testify about the use -- the writing of noncontrolled substances with the controlled substances by physicians?

A. Yes. I addressed that issue as it related to -- tied in with abuse.

Q. And you stated, did you not, that usually those noncontrolled substance prescriptions were not related?

A. I said quite often, I believe.

Q. So is constipation one of the frequent side effects of the use of opioids?

A. Yes.

Q. So anything -- any prescription that related to relieving constipation you would consider that a related prescription?

A. It could be, yes.

Q. Ibuprofen. Now for people who are taking opioids and they have some additional pain and they don't want to take another opioid they would take a large dosage of ibuprofen, couldn't they?

A. Not real large but ibuprofen could be used for minor pain.

Q. So ibuprofen would be related?
A. Could be.
Q. And Docusate and Colace are prescribed and used for the treatment of constipation, aren't they?
A. Docusate?
Q. Excuse me?
A. Docusate?
Q. That the way you pronounce it?
A. That's the way I do.
Q. Then docusate and Colace?
A. Yeah.
Q. Now, you said that back pain is hard to diagnose. Do you remember saying that?
A. Yes.
Q. And obviously if somebody pulls a muscle that's going to heal in a week or so oxycodone would not be the appropriate medication for such a patient; is that right?
A. Usually, yes.
Q. If somebody has some kind of pain -- spinal pain and has had it for a year or two years, that is a different kind of back pain that may be more likely to be treated or should be treated with oxycodone; isn't that right?
A. Depending upon what's causing the pain that's a possibility, yes.
Q. Now, I guess there are some pharmacists that are nonprofit

but generally it's your experience that pharmacies are -- exist as a moneymaking enterprise; is that right?
A. Yes.
Q. And there's nothing wrong with a pharmacist -- nothing illegal with a pharmacist trying to make as much money as possible as long as they do it legally; is that right?
A. Yes.
Q. Now, you have heard of a company that has bought some limited type of medication and increased the cost of that medication by five hundred times. Have you read that recently?
A. Yes.
Q. That's not illegal, is it?
A. No.
Q. That's pretty nasty and perhaps unethical but it's not illegal; is that right?
A. That's correct.
Q. Now, medical insurance companies, health insurance companies, when they pay for prescriptions, do they pay for the full retail cost of prescriptions or do they pay less than the full retail cost of prescriptions?
A. It depends on the contract between the pharmacy and the insurance company.
Q. Well if the pharmacy doesn't have a contract with the insurance company, right, would that pharmacy accept the insurance?

Don't answer that question.

Is there any law that prevents the pharmacy from charging -- overcharging for -- withdrawn.

Is there any law in Ohio that prevents a pharmacy from doubling or tripling its price for medication because there's a shortage of medication and they're able to get that price?

A. Not in the drug laws. I'm not familiar with the financial price gouging type laws. Those are not in my area.

Q. And is there anything that you know is illegal for a physician to -- is there any -- withdrawn.

Is there anything illegal for a pharmacist or someone who manages a pharmacy to inform a doctor that they're having difficulty in obtaining a certain type of medication and will only be able to do it if they get noncontrolled substance prescriptions as well?

MR. TEHRANI: Objection, your Honor. If we could rephrase the question on that.

THE COURT: Yes. If you'll rephrase the question.

Q. Is there any -- is there any law that prevents anyone from a pharmacy in suggesting to a doctor's office to prescribe noncontrolled substances to help them obtain the necessary, medically necessary controlled substances?

A. I can't imagine --

Q. That's a yes-or-no question, sir.

A. No. It's not a yes-or-no question. I can't answer that

yes or no.

Q. Answer this question. Is it illegal for a doctor to prescribe a non-medically necessary noncontrolled substance?

A. In many states, yes, it is.

Q. Is it illegal in Ohio?

A. Yes.

Q. What is the crime in Ohio?

A. Corresponding responsibility rule again. Legitimate medical purpose. In Ohio that applies to all prescriptions not just controlleds. So if it's not for a legitimate medical purpose it's a false prescription which in Ohio happens to be a felony.

Q. Thank you.

Now is there any -- is that statute in the federal law?

A. Well DEA only deals with controlled substances, so.

Q. So it may be a violation in Ohio but it's not a violation under the Controlled Substance Act; is that correct?

A. Federal, no.

Q. Am I correct?

A. Yes.

Q. And do you know if it's illegal in Florida?

A. No.

Q. Do you know if it's illegal in New Jersey?

A. No. I do not know.

MR. SCHMIDT: May I have just one moment, your Honor. The Court's indulgence.

(Pause)

Q. Now, the only time that you actually practiced as a practicing pharmacist in a nonhospital setting was when you worked at your parents' pharmacy; is that correct?

A. Yes.

MR. SCHMIDT: I have no further questions.

THE COURT: Cross-examination on behalf of Mr. Kalaba.

MR. FISHER: Thank you very much, your Honor.

CROSS-EXAMINATION

BY MR. FISHER:

Q. Good afternoon, sir.

A. Good afternoon.

Q. How are you?

A. I'm still here.

Q. That you are. I will try to make it not too much longer.

You talked a lot on direct examination about how oxycodone can be abused and other substances like that can be abused. Do you remember that testimony?

A. Yes.

Q. Can you tell us in which ways -- what is oxycodone used for? What are its medical purposes? Why do people need oxycodone?

A. For the treatment of pain.

Q. What kinds of pain?
A. As was previously covered, moderate to severe but in my opinion more towards the severe end for straight Oxycontin -- oxycodone, excuse me.
Q. I'm talking about what kinds of things cause patients to need oxycodone? I know pain. But how do patients get the pain that causes them --
A. Cancer is the main one that causes very severe pain.
Q. What else?
A. Some types of prolonged injuries requiring frequent surgeries or something else.
Severe pain is not a real common occurrence.
Q. Didn't we just say earlier that it was actually moderate to severe pain?
A. That's what I said, that the package insert says moderate to severe.
Q. But you disagree with that?
A. Pure oxycodone I do not think is as indicated now. If we're talking about the combination of oxycodone with acetaminophen or Tylenol that's been widely used for moderate pain and fairly effectively. So it depends on the product we're talking about.
Q. Just to be clear about your answer. Are you saying one pill that contains both oxycodone and some other substances or are you talking about several prescriptions?

A. No. I'm talking about the drug that -- I was asked about on direct called Percocet which is a combination of the two with lower doses of oxycodone in them.
Q. Okay. So let's get back to some of the things that can cause a patient to need oxycodone. If somebody had a surgery, oxycodone might be helpful after the surgery, correct?
A. It might. I have not seen it widely used that way. But it could be post-op short term.
Q. If somebody has severe pain in their neck, oxycodone could be helpful, right?
A. Depending upon what the cause was. Short term, perhaps.
Q. You mean you don't believe that oxycodone could be used at all for long-term pain?
A. I'm suggesting that the examples you've given me are also amenable to other treatments as well. So if we're talking about a combination of all sorts of therapies, that's a possibility.
Q. But you don't believe oxycodone can be helpful for use for long-term pain?
A. Not by itself for certain kinds of long-term pain.
I think that we've already talked about tolerance, dependence, addiction. I know that the practice among pain specialists is to alternate when tolerance develops. On direct I was asked about if the drugs were interchangeable. I'm being asked a question that really doesn't relate to what happens.

And so, yeah, Oxycontin is useful for the treatment of pain. That's what came --

Q. I'm trying to get at -- and you gave me a really long answer to a pretty short question -- I'm trying to get at if somebody has long-term severe pain you don't think oxycodone could be helpful to treat that? It's a pretty yes-or-no question.

A. Okay. It can. Depends on the cause of the pain is what I'm trying to get across.

Q. If somebody has lumbar disk displacement, oxycodone could be helpful to treat that kind of pain, correct?

A. Short term, yes.

Q. If somebody has neuralgia, oxycodone could be helpful to treat that kind of pain, right?

A. It could.

Q. If somebody has neuritis, oxycodone could be helpful to treat that kind of pain, correct?

A. Yes.

Q. If somebody has radic-- I'm going to spell it because I can't pronounce it. R-A-D-I-C-U-L-I-T-I-S. Do you know how to pronounce that?

A. Radiculitis.

Q. Radiculitis. Is that something oxycodone can help with, if somebody has pain from that?

A. I hate to admit it but I can't remember what radiculitis

is. So the answer is maybe.
Q. That makes two of us on that one. Neither of us are doctors, right?
A. That is correct.
Q. Cervical disk displacement. Is that something that oxycodone can help with if somebody has a lot of pain from cervical disk displacement?
A. It can help.
Q. Thoracic or lumbar neuritis? Is that something oxycodone can be helpful in the treatment of?
A. It could.
Q. Thank you.

You talked about on direct examination and also on cross-examination about how pharmacists have certain corresponding liability, correct?
A. Yes.
Q. But the pharmacy owner doesn't have that same corresponding liability, correct?
A. Under New Jersey law, yes, they are both equal -- the pharmacist in charge, as I testified previously, the pharmacist in charge and the owner are equally liable for violations of the pharmacy practice.
Q. But all of those things you talked about on direct examination about all the things a pharmacist is trained in and the responsibilities the pharmacist has and the continuing

education, those are all things that the pharmacist has to do to stay abreast of the law, look at prescriptions, etc., etc., right?

A. Yes.

Q. The pharmacy owner doesn't have those same obligations, correct?

A. Not for the continuing education and those kind of things, no.

Q. And a manager of a pharmacy doesn't have the same kind of obligations as a pharmacist in a pharmacy, correct?

A. That is correct.

Q. In fact, it's not illegal or against the law for a pharmacy manager to manage a pharmacy even if he doesn't have prior pharmaceutical experience, correct?

A. Depends on what you mean by manage.

Q. So it would be the day-to-day operational manager of a pharmacy, if somebody is the day-to-day operational manager of pharmacy they are not required to have prior pharmaceutical experience in order to get a -- to run the pharmacy, correct?

A. Not completely.

Q. What do you mean by that, sir?

A. Thank you for asking.

Q. No problem.

A. If we're talking financial aspects, I'll agree with you. If we're talking about drug decision making, professional

decision making, no, they can't be involved in that. And that's all what takes place in managing a pharmacy. So they can be responsible for some of the areas.

Q. Okay. I'm saying it doesn't disqualify someone from being a manager if they don't have prior pharmaceutical experience. That's what I'm asking you.

MR. TEHRANI: Your Honor, I believe he answered the question.

THE COURT: Sustained.

MR. FISHER: Maybe I misunderstood. Let me ask it a different way then.

BY MR. FISHER:

Q. So if somebody filled out a pharmacy application and said the manager of the pharmacy has no prior pharmaceutical experience, would that person automatically be barred from managing the pharmacy?

THE COURT: Counsel, I think that what the witness has been saying is that it depends upon how you define manage.

MR. FISHER: Oh, okay.

Q. So, somebody who was -- let me withdraw that question for a second.

You were a part of the Ohio Board of Pharmacy for some time, right?

A. Yes.

(Continued on next page)

BY MR. FISHER:
Q. So there would come times in your duties as being part of the Ohio Board of Pharmacy that you would have to go to particular pharmacies to investigate pharmacies, right?
A. Yes.
Q. To see if everything was being run properly, right?
A. Yes.
Q. If there were any problems in the way the pharmacy was running, correct?
A. Correct.
Q. And if you came there and you learned that there were some things that were happening which really weren't, you know, up to standards, you would note that, correct?
A. Yes.
Q. And if you learned that, for instance, a pharmacy manager didn't have a lot of experience running pharmacies, you would note that, correct?
A. There wouldn't -- in Ohio there would not have been one that wasn't a pharmacist.
Q. You mean in Ohio you have to be a pharmacist to be a manager?
A. Most states to be the person who signs that application that you referred to, it has to be a pharmacist who serves as the pharmacist in charge.
Q. I don't mean the pharmacist in charge.

A. We are back to -- I don't know what you mean by "manager," then, because the pharmacist in charge I've already testified is responsible to see that the pharmacy is run in a legal, professional manner, that the policies and procedures are in place. It's the pharmacist in charge that is charged with that.

Q. OK. Maybe I misunderstood you.

So when I say "manager," I'm talking about somebody who is in the pharmacy day to day. Are you with me so far?

A. Sure.

Q. A layperson, not a pharmacist, not a doctor. Are you with me?

A. Of course.

Q. This person had some responsibility in the hiring and firing of some of the employees in the pharmacy.

A. OK.

Q. Including cashiers, pharmacy techs. Are you with me so far?

A. Yes.

Q. Had some input in who was to become the pharmacist in charge, right?

A. OK.

Q. Are you with me so far?

And is reporting back to the actual owner of the pharmacy and taking directions from the owner of the pharmacy

but otherwise is managing all of the employees in the pharmacy. Do you understand what I'm saying?
A. Kind of like a human resources place.
Q. I guess so, yes.
A. OK.
Q. OK. And if you went to one of your inspections to one of those pharmacies in Ohio and you found that that person who was doing that management and that day-to-day activity didn't have much experience in the pharmaceutical industry, would you note that in your investigation?
MR. TEHRANI: Objection. Relevance.
THE COURT: Overruled.
You may answer.
A. That's a situation that is way too theoretical as far as I'm concerned. We hold the pharmacist in every state I know of, hold the pharmacist accountable for what goes on in that pharmacy department. There may be a manager in there to do some of the financial tasks, the human resources task, but the ultimate decision on what goes in and comes out of that pharmacy is assigned to the pharmacist in charge.
THE COURT: Perhaps you should describe what are the tasks of a pharmacist.
THE WITNESS: That's basically what we went through on direct. In other words, being in charge of the prescription process, and then the pharmacist in charge is responsible to

make sure the policies and procedures are in place, to make sure that the pharmacy is operated legally and in the best interest of the patients. So -- and nobody is permitted to be in the pharmacy unless the pharmacist is present.

THE COURT: So what are key decisions made by a pharmacist?

THE WITNESS: It depends on the situation. In some, the pharmacist in charge is the one that basically decides what drugs the pharmacy is going to stock, how they're going to -- how many they are going to purchase, what drugs, you know, get dispensed. They have personnel duties so that if their technicians or pharmacists are not acting legally, they have duties to see that that's taken care of.

Yeah, there are nonpharmacist managers in a lot of the pharmacies that we are aware of that cover the store, the pharmacy, but the actual decision making about drugs in the pharmacy belongs to the pharmacist in charge. That's why I'm just getting a little confused on where we're going with manager, nonpharmacist manager versus pharmacist. That's just not a situation in terms of decision making that I've ever seen. I've seen lots of situations where the store manager -- in fact, most of the time the store manager is not a pharmacist, but the store manager has no ability to access the pharmacy in the absence of a pharmacist.

BY MR. FISHER:

Q. Understood. Thank you.

Have you ever done one of these Board of Pharmacy inspections and found out that some things were not right in the running of the pharmacy, right? We've already established that, yes, that happened sometimes, right?

A. Yes.

Q. And did you ever find out that there are some things that that pharmacy could be doing a lot better?

A. Yes.

Q. Did you ever educate the pharmacists or the technicians about things that they could be doing to make that pharmacy run smoother?

A. Yes.

Q. And educate them on things that they could be doing to better verify prescriptions?

A. Yes.

Q. And educate them on things that they could be doing to try to avoid diversion of medications?

A. Yes.

Q. I mean, that, in fact, is part of your duties and responsibilities at the Board of Pharmacy, correct?

A. It was for us, yes.

Q. I mean, that's one of the most important goals of the employees of the Board of Pharmacy is to do everything you can to try to avoid diversion of medications, correct?

A. And to ensure compliance with the law, yes.
Q. And by ensuring compliance, the ultimate goal is to try to avoid diversion, right?
A. Yes.
Q. So if you could go in and do an inspection and try to educate the people who are working there about things that they could be doing better, that's something that you would do, right?
A. That's something we did quite frequently.
Q. You would do it all the time?
A. No.
Q. Oh, I'm sorry. Quite frequently?
A. Yes.
Q. And the main goal, again, is to stop diversion, right?
A. Yes.
Q. OK. You testified on direct examination about a pharmacy tech in the absence of a pharmacist is not allowed to dispense medications, right?
A. Yes.
Q. That is against the rules, right?
A. Yes.
Q. It is actually breaking the law, right?
A. It isn't allowed and I'm pretty sure elsewhere.
Q. OK, state law?
A. Yes.

Q. Not federal law?
A. Well, no, it is a violation of the federal regulations, too.
Q. OK. So breaking of the rules breaking the law. But if a pharmacy tech dispenses meds without the pharmacist present, does that automatically mean that that prescription was not medically necessary?
A. No.
Q. No. In fact, that could be a perfectly good medically necessary prescription written by a perfectly good doctor, correct?
A. It could.
Q. And that prescription if it was filled without the pharmacist present, it doesn't automatically mean it was not for medical necessity, correct?
A. That's correct.
Q. In fact, if you learned that, yes, the pharmacy tech filled it but actually that doctor who wrote the medication was licensed, right, what if you learned that? That would help you determine whether or not that script was for a medical necessity or not, correct?
A. If that's what I was looking for.
Q. Well, that would be one thing you could look for, right?
A. I could but I wouldn't.
Q. What do you mean?

A. If the tech dispensed it, the tech violated the law.
Q. Yes. Oh, so you don't care about medical necessity; is that not important in the determination of what's going on?
A. Not in the determination of whether that tech acted legally or not.
Q. So at the Board of Pharmacy, that's really the only thing you are concerned about is whether the people at the pharmacy are acting legal or not, or is the ultimate goal, again, to prevent diversion?
MR. TEHRANI: Objection, your Honor.
THE COURT: Overruled.
A. The Board of Pharmacy's role is to protect the health and safety of the citizens of that particular state by ensuring that people follow the laws and rules correctly, and if a technician is dispensing drugs, they are violating the law and the action would be taken against the technician. The validity or not of the prescription does not enter into that particular decision.
Q. I understand. Did the government ask you as part of -- withdrawn.
Did you have to review a lot of documents to prepare for this case?
A. No.
Q. None at all?
A. No.

Q. Did you have to meet with the government at all to prepare for this case?
A. Just last night when I got here.
Q. Did you have to speak with them on the phone at all to prepare?
A. Yes, two phone conversations.
Q. Did the government ask you to review any of the credentials of the pharmacists in charge at Plainfield Pharmacy?
A. No.
Q. So as sit here today, you don't know whether or not, for instance, Dan Podell had a valid license or not?
A. I do not.
Q. Or any of the other pharmacies involved in this case, did you review any of those pharmacists' licenses to see if they were actually a valid license or not?
A. No, I did not.
Q. Did the government ask you to check and see whether any of the doctors who were prescribing prescriptions relating to this case actually had valid medical licenses or not?
A. No.
Q. Did the government ask you, as part of your preparation for this case, to review any of the medical charts of any of the patients who received prescriptions in connection with this case?
A. No.

Q. Did the government ask you, in your preparation of this case, to review any of the actual prescriptions filled in connection with this case?
A. No.
Q. Just to be clear, I am talking about the paper prescriptions that were used in this case, did the government ask you to review any of those?
A. No.
Q. Did the government ask you to review any of the patients' contracts having to do with this case?
A. No.

MR. FISHER: Judge, I am about to go into another topic that is probably about 20 minutes or 30 minutes, so is it OK if we end now?

THE COURT: All right. Members of the jury, we will resume with this witness tomorrow at 9 a.m.

Remember that you are not allowed to discuss the case amongst yourselves or with anyone else. Don't permit anyone to discuss the case in your presence.

Sir, you may step out.

THE WITNESS: Thank you.

(Continued on next page)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x

UNITED STATES OF AMERICA, New York, N.Y.

v. 13 Cr. 0794(AT)

PAUL WISEBERG and ROBERT KALABA,

Defendants.

----------x

October 15, 2015
9:00 a.m.

Before:

HON. ANALISA TORRES,

District Judge

APPEARANCES

PREET BHARARA
United States Attorney for the
Southern District of New York
BY: DANIEL B. TEHRANI
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JANE H. FISHER-BYRIALSEN
Attorneys for Defendant Robert Kalaba

- also present -

Elizabeth Joynes, Government Paralegal
Task Force Officer Brian Hammarstrom

(Jury present)

THE COURT: You may be seated.

Good morning, jurors.

I apologize for the 18-minute delay in getting started. There were certain things that I needed to take care of before we started. It's not the fault of either side.

We're going to continue with the cross-examination of Mr. Winsley.

Remember that you're under oath.

Go ahead.

CROSS-EXAMINATION CONTINUED

BY MR. FISHER:

Q. Good morning, Mr. Winsley.

A. Good morning.

Q. You spoke yesterday about controlled substances. You have to answer the question.

A. I didn't know there was a question but yes, I did speak.

Q. And you also spoke about noncontrolled substances?

A. That I did.

Q. There's a difference, obviously between controlled substances and noncontrolled substances, right?

A. Legal and pharmacologically, yes.

Q. And before the controlled and noncontrolled substances make their way to the pharmacy they have to come from the distributor first, correct?

A. Yes. A distributor. Either a wholesaler or manufacturer.
Q. Now the distributor -- isn't it true that the distributor also has certain rules and protocols that they follow on how they distribute the drugs and to whom they distribute the drugs?
A. Yes. They have legal requirements that they have to follow as well.
Q. If you can answer a question with a yes or a no, I would appreciate that.

Do you understand?

A. I understand that.
Q. So let me just ask that question again.

Distributors have certain rules and protocols that they need to follow and want to follow when they distribute their drugs to the pharmacies, correct?
A. Yes.
Q. And one of those protocols and rules that have recently come about is that there are some distributors who are making actual policies about the percentages of controlled versus noncontrolleds that they will distribute to pharmacies; isn't that right?
A. Partially.
Q. So now you can explain what you mean, please?
A. You said rules and protocols. There are no rules that mandate that they set percentages. That is not a legal

requirement. That is something that some of the wholesalers have chosen to do on their own.
Q. So they have initiated protocols but not rules?
A. Well they can't promulgate rules but, yes, they have set up their own policies and procedures to choose how they distribute drugs. But that's their doing. It is not any legal requirement.
Q. So --
THE COURT: Is that on an industrywide basis or is that company by company?
THE WITNESS: The legal requirement is that wholesalers have to have a method to determine that a sale to a pharmacy, for example, is legitimate.
THE COURT: So my question is these protocols that you're speaking of, is it an industry group that gets together and they have joint protocols or is it individual companies deciding on their own individual protocols?
THE WITNESS: Can I say almost both.
There is an association of wholesalers, and they talk. Each wholesaler has set up its own protocol which to my -- in my experience has varied from pharmacy to pharmacy, from location to location, but they have methods to try to determine suspicious orders, which they are required to do. It's just that the percentages that he asked about are set by the individual wholesalers on an individual customer basis. It's

not something that is required and, in fact, if I may, it's led to problems that I'm sure we'll address here shortly.

BY MR. FISHER:

Q. Tell me what kinds of problems.

A. The percentages have been set arbitrarily. They are not based upon any reason or basis of fact and they were set as a result of some of the cases where wholesalers obviously failed in their duty to report suspicious orders, and I speak from personal experience in Ohio as well as knowledge of some of the federal cases, having participated in some of those.

Q. So is it fair to say that sometimes pharmacies are at the mercy of these wholesalers who have these arbitrary rules set in place -- in other words, if they want to get controlled drugs from the distributors they're going to have to do it in the arbitrary percentages that the distributors set up and make those rules about?

A. That's -- yes. That's what has been happening.

Q. So, in other words, they will -- just to be clear. The wholesalers will actually say to the pharmacies: We will only sell you X percentage of controlled versus X percentage of noncontrolled?

A. I haven't heard the relationship.

I've heard that they've put limits on the amount of controlleds that they will sell.

Q. They don't -- so limits on the amount of controlled being

that you can only get so many controlleds, right? Percentages?
A. You can only buy so many bottles of this drug at one time.
Q. So you mean you've never heard of a situation where the wholesaler is saying to the pharmacy: You can only have, for example, 20 percent controlled, 80 percent noncontrolled or you could only have two controlled for every one noncontrolled or vice versa?
A. I've never had anybody complain to me about that particular situation anywhere I've been in the country.
Q. So it's the arbitrary limits on the number of pills that pharmacies can get?
A. All that I've ever heard about is, as an example, you can have three bottles of Oxycontin a month and that's it; or you can have five bottles or ten -- you know, whatever the wholesaler has put on it.

But all of the complaints I have received all over the country have been based upon buying controlled substances and the number of bottles that the pharmacy can obtain. And once they reach their limit, the wholesalers have refused to sell more to them.

Q. And you would agree you've already said that those numbers are set arbitrarily sometimes?
A. And I've said that nationally in all my talks because it comes up at every talk that we're at with pharmacists.
Q. So you would agree with me that these kinds of arbitrary

limits can lead to patients who really need the medicines not being able to get them?
A. I have heard about that quite frequently, yes.
Q. Filling mail order prescriptions is certainly not against the law, correct?
A. Correct.
Q. It's not against the law in the State of Ohio?
A. No.
Q. It's not against the law in the State of Florida?
A. No.
Q. It's not against the law in the State of New Jersey?
A. No.
Q. You're aware that CVS has their own mail order program?
A. Yes.
Q. Can you tell us how their verification process works at CVS for their mail order program?
A. I've never been in Caremark.
Q. Can you tell us how Walgreens' mail order prescription works?
A. I've been in Walgreens but not their mail order.
Q. So do you know the verification procedures that they use to verify these scrips for CVS or Walgreens?
A. Not those two.
Q. When a pharmacy receives a mail order prescription the pharmacist does not -- I'm sorry. Withdrawn.

When a pharmacy receives a mail order prescription the pharmacist does have certain obligations, correct?
A. Correct.
Q. Specifically, the pharmacist filling the prescription has a corresponding responsibility to insure the prescription he or she is filling was written for a legitimate medical purpose and in the course of the doctor's professional practice, correct?
A. If you would substitute "practitioner" or "prescriber" for "doctor," yes.
Q. I could not hear you.
A. If you would substitute "practitioner" or "prescriber" for "doctor," yes, because it could be a dentist prescription.
Q. There is no per se definition of the term legitimate medical purpose, correct?
A. Like federal rules and so forth?
Q. Correct.
A. No, there is not.
Q. There is no per se definition of the term in the course of the doctor's professional -- I'm sorry, in the course of the practitioner's professional practice, correct?
A. No -- I mean yes. Correct. No, there is not.
Q. Although there are no per se definitions of these terms, there are things that a pharmacist can do in order to fulfill their obligations in this regard. Would you agree with that?
A. Yes.

Q. And there are things that pharmacy staff can also do to fulfill these same obligations, correct?
A. No.
Q. To help the pharmacist fulfill these same obligations?
A. Yes.
Q. In other words, when a pharmacy receives a mail order prescription there are certain steps that can be taken to attempt to insure that that prescription was written for a legitimate medical purpose, correct?
A. Yes, there are.
Q. And in the course -- and also that the prescription was written in the course of the practitioner's medical practice, correct, or professional practice?
A. Yes.
Q. And there are certain protocols that can be used in order to achieve this goal, correct?
A. Yes.
Q. So let's discuss what some of those protocols could be. Are you with me?
A. So far. I'm still here.
Q. The pharmacist and/or the pharmacy staff can check to see that the doctor whose name appears on the prescription actually has a valid medical license, right?
A. Yes. As long as that information is made available to the pharmacist. It's the pharmacist's ultimate decision. So, yes,

somebody can check.
Q. So one of the things that they can do is to check to see if the name that's written on the prescription, the doctor's name actually has a valid medical license or not, correct?
A. Correct.
Q. And they can also -- the pharmacist and/or the pharmacy staff can inspect the physical prescription itself to see that it's not been tampered with in any way, correct?
A. That's the ultimate responsibility of the pharmacist.
Q. Okay. But certainly -- when I ask these questions I mean a pharmacy staff person might check it, show the doctor, tell the doctor about any imperfections or problems, right?
A. No.
Q. I'm sorry. When I said "doctor" I meant pharmacist.
A. Yes, they can. But the pharmacist needs to the verify that.
Q. It's the pharmacist that has the ultimate -- we get that, sir. It's the pharmacist that has the ultimate responsibility, right?
A. Absolutely.
Q. And it's the pharmacist who should be trying to insure that the prescription has not been forged, right?
A. Yes.
Q. And the pharmacist to some degree relies on their staff to help them do a lot of these things, right?

A. Yes.
Q. And they -- the pharmacist also bears the responsibility to insure the signature actually comes from that physician, correct?
A. To the best of their ability.
Q. And the pharmacy and through the help of the -- the pharmacist or through the help of the pharmacy staff can check to see that the name on the prescription actually matches the identification card of the patient who sent in the mail order prescription, right?
A. Yes.
Q. That is one way to help determine whether or not this prescription is valid, right?
A. It's one of the steps, yes.
Q. Now, all of these checks and balances I've mentioned to you so far are not musts when it comes to filling mail order prescriptions, correct?
A. No. That's not correct.
Q. Well we've just established that there are no per se federal rules in regard to what must be done to insure that a prescription was filled for a legitimate medical purpose, correct?
A. They're not itemized. But the pharmacist is responsible for -- and that's not federal, that's state -- the pharmacist is responsible to interpret the prescription to make sure it

meets all legal requirements. And all of those that you mentioned are legal requirements.

Q. Correct me if I'm wrong here. When I'm asking these questions, I'm going on the premise that we've already established that there are no federal rules or lists of musts or dos and don'ts, right, for how a pharmacist is supposed to achieve these goals, correct?

A. Almost. There are rules about what a legitimate prescription must contain.

Q. That's correct. But there are no rules under the federal rules that you know about, right, the federal rules that govern pharmacies, right, the federal rules promulgated by the DEA, there are no federal rules about what must be done to make sure that a prescription is written for a legitimate medical purpose, correct?

A. That itemize step by step?

Q. Yes.

A. No.

Q. So all these things we've been talking about, these protocols, these are not musts under the federal rules, correct?

A. I think we're playing with words there. We have a rule that specifies --

MR. FISHER: Your Honor, I move to strike the witness's testimony as nonresponsive and ask you to instruct

the witness to please answer the questions that I pose to him.

THE COURT: The answer is stricken. Please just answer the question.

Q. These are not musts, correct? Under the federal rules these are not musts?

A. These are not itemized in the federal rules.

Q. Thank you.

That being said, this is my next question, that being said, all of these things we have just gone through would be helpful or useful for the pharmacist and/or the pharmacy staff to do in order to fulfill their corresponding responsibility under the law, right?

A. Almost.

Q. These are good ideas, correct?

A. I think that you need to insert the word "necessary."If you do, my answer is yes. "Helpful" doesn't make it.

Q. These are things that are useful or helpful in order for a pharmacist to fulfill his corresponding responsibility under the law, correct?

MR. TEHRANI: Your Honor, he's answered the question.

MR. FISHER: I don't believe that he has.

THE COURT: I agree that he has not answered the question.

Mr. Winsley, answer the request.

THE WITNESS: The way you worded the question my

answer is no.
Q. So these are not things that would be helpful or useful for that pharmacist to determine whether or not the prescription was written by a -- for a legitimate medical purpose? Is that what you're saying?
A. I'm saying it depends on who did them. So my answer is yes or no, depending upon who did them.
I'm not sure where we're going here.
MR. FISHER: Move to strike that portion of the witness's testimony that is nonresponsive to my question, your Honor.
THE COURT: I will strike everything from "I'm not sure."
Q. So, again -- let me ask you this. So you're not sure whether it is useful or helpful for the pharmacist to undergo this checklist of things we just talked about in order to determine whether or not this prescription was filled pursuant to a legitimate medical necessity?
A. Thank you. I will say that it is.
Q. These things are helpful or useful to do?
A. The way you just expressed that, yes, sir, you are correct.
Q. Let's talk about some additional things a pharmacist can do in order to fulfill their corresponding responsibility under the law. Are you with me?
A. Yes.

Q. The pharmacist -- if the pharmacist has additional questions about the prescriptions, one thing they can do is to call the doctor's office, correct?
A. Yes.
Q. And when calling the doctor's office they can further verify the legitimacy of the prescription in various ways. Would you agree with me?
A. Yes.
Q. And also the pharmacist can have a pharmacy staff member call these doctors' offices to gain some information, correct?
A. Partially.
Q. And the pharmacist and/or the pharmacy staff can try to verify that the prescription they receive was actually written by the doctor listed on the prescription, correct?
A. Yes.
Q. And they can try to verify with the doctor's office that the patient listed on the prescription was actually seen by that doctor, correct?
A. Yes.
Q. And they can verify that the medicine written on the prescription matches the records at the doctor's office, correct?
A. The pharmacist can do that?
Q. Correct.
A. Yes.

Q. Or the pharmacy tech can call up and find that information out and tell the pharmacist?
A. If there's a question about drugs, no, sir. The pharmacist can do that.
Q. So would it not be helpful or useful for the pharmacist to learn from the pharmacy tech that I just called the doctor's office and I spoke to so and so at the doctor's office and they told me that, yes, oxycodone 30 milligrams was prescribed, would that be helpful or useful for the pharmacist in making the determination about whether or not these medicines were prescribed for a legitimate medical purpose?
A. No, it would not.
Q. That information would not help the doctor out, is that -- or, I'm sorry, the pharmacist out?
A. Not if the tech did it.
Q. The pharmacist and/or the pharmacy tech can find out whether the number of pills matches what's on the doctor's records, correct?
A. Yes.
Q. And the pharmacy tech or the pharmacist can call up and find out whether the strength or the milligrams is also a match?
A. Perhaps with the tech.
Q. And, again, all of these checks and balances I've mentioned so far are not musts or absolute requirements under the federal

regulations, they are not promulgated somewhere when filling mail or prescriptions, correct?
A. That's correct.
Q. That being said, all of these steps we've just gone through would be helpful for the pharmacist in order to be able to determine whether or not he is fulfilling his corresponding liability under the law?
A. Given my previous answers of probably and no, yes.
MR. FISHER: Your Honor, I move to strike the witness's testimony, please.
THE COURT: The answer is stricken.
MR. FISHER: Thank you.
Q. Can you try to answer that question again, please.
A. If you'll ask the question better, yes.
Q. That being said, all of these steps we have just gone through would be helpful for the pharmacist and the pharmacy staff to do in order to fulfill the pharmacist's corresponding liability under the law?
A. The way that's worded my answer has to be no.
Q. Why is that?
A. You throw in "pharmacy techs" and I've already said that some of the duties the pharmacist needs to do himself or herself. I cannot agree to a sentence that has both.
Q. So just to be clear you're saying it wouldn't be helpful or useful for the pharmacy tech to relay some information he's

learned to the pharmacist?
A. May I explain?
Q. Can you answer that question with a yes or no?
A. No.
Q. Okay. Go ahead and explain.
A. Some of the items that you have asked about, the tech has the ability to call and ask. When it gets down to the drug names, strength, directions for use, if there's a question there, that's the pharmacist's responsibility.

If the pharmacist made that call, yes.

If the tech says "the doctor's office said this," the pharmacist can't really use that if the pharmacist had a question. The pharmacist is -- it's necessary to make that call because if there is a correction or a change the pharmacist has to speak with the prescriber in order to do that.
Q. What if the pharmacy tech says there is no correction or change, tells him I called the doctor's office, they tell them this is exactly what they wrote?
A. If the pharmacist had a question, then they'd still have to call. If there was no questioner anywhere then, sure, that's -- I mean that doesn't -- it's a meaningless conversation at that point.
Q. It's meaningless because -- I don't understand. Why is it meaningless?

A. If the pharmacist has questions, they have to deal with them. Just calling the doctor's office to verify that it was written, we already discussed during my direct, is not useful in any way.
Q. So calling the doctor's office to verify this doctor actually wrote that prescription is not useful information for the pharmacist?
A. No. Because the doctor's office will verify if they wrote it.
Q. Why do pharmacists ever call doctors' offices to verify these things?
A. If they have questions.
Q. Should the pharmacist actually go down to the doctor's office and inspect the doctor's office himself?
A. No.
Q. Should they be -- should they request to be there during the medical examination?
A. No.
Q. Right. They call doctors' offices all the time to try to verify prescriptions, right?
A. No. They call to get information to clarify prescriptions.
Q. So when pharmacists in the normal course of their duties call to doctors' offices they are not asking the doctor's office: Does this scrip in my hand comport with what your file said?

A. Not unless they have a concern or a question, there is no need for them to do that.
Q. Right. They don't even call up at all if they have no concern or question, correct?
A. That's correct.
Q. But one of the things that can be useful is to make sure when they call up this scrip is actually the same as what the doctor wrote, right? It wasn't altered or changed?
A. (No response).
Q. Right?
A. If they thought it was altered or changed they'd call and that would be the pharmacist's responsibility.
Q. Right.
A. Okay.
Q. Try to call or verify that it wasn't altered or changed, right?
A. If he had a suspicion that it was.
Q. If he didn't have a suspicion he wouldn't call at all, correct?
A. Correct.
Q. Let's talk about some additional checks and balances a pharmacist and/or pharmacy staff can do to comply with the pharmacist's corresponding responsibility under the law. Okay.
The pharmacy can require that the doctor's office forward a letter of medical necessity for the patient who is

attempting to fill the prescription, correct?
A. No. I don't know that that's a requirement.
Q. I'm not saying it's a requirement. I'm saying this is another additional step a pharmacy can do to try to meet its corresponding liability under the law?
A. They can try that.
Q. This is another step they can undergo, right?
A. Yes.
Q. And the pharmacy can require that the doctor's office provide the pharmacy with a signed patient agreement form, correct?
A. Yes, they can.
Q. And/or a patient contract signed by the patient, right?
A. They can.
Q. The pharmacy staff can also keep an incident log at their pharmacy, correct?
A. Would you explain.
Q. Sure. A record they -- they can keep a record at the pharmacy noting doctors or patients or prescriptions or doctors' offices that they have found to have red flags in the past, they can keep that incident log on file so as to look out for those kinds of things in the future?
A. Yes.
Q. That is a check and balance that a pharmacy can do in order to try to fulfill its corresponding liability under the law,

correct?
A. Corresponding responsibility, yes.
Q. Thank you.
Now, all of these things we have talked about are steps that a pharmacy can take to try to meet their professional obligations, correct?
A. Yes.
Q. Now, again, none of these things we have gone through are absolute requirements for filling mail order prescriptions under the federal law, correct?
A. Yes.
Q. Nor have we gone through an exhaustive and a comprehensive list of all of the steps a pharmacy and/or a pharmacy staff can take to verify the legitimacy of a mail order prescription, correct?
A. Yes.
Q. Because, of course, a pharmacist and/or a pharmacy staff could always do more to verify prescriptions, right?
A. Yes.
Q. But the law does not require a pharmacy or a pharmacist -- I'm sorry. Let me withdraw that.
The law does not require a pharmacist or a pharmacy staff to do everything possible to insure the legitimacy of prescriptions received at their pharmacy, correct?
A. Correct.

Q. And the law does not require a pharmacist or pharmacy staff to take every conceivable measure to insure the legitimacy of the prescription that they fill, correct?

A. Correct.

MR. FISHER: Thank you. No further questions.

THE COURT: Will there be redirect?

MR. TEHRANI: Briefly, your Honor.

REDIRECT EXAMINATION

BY MR. TEHRANI:

Q. Good morning, Mr. Winsley.

A. Good morning.

Q. Does federal law impose requirements on pharmacists?

A. Yes.

Q. Were those the requirements that you testified extensively about on direct?

A. Yes.

(Continued on next page)

Q. And must the pharmacist comply with those obligations?
A. Yes.
Q. You were asked questions just now about verification of prescriptions. What do you understand "verification" to mean?
A. Verification is a lot more than we just covered. Verification means that the pharmacist needs to assure himself or herself that it is for a legitimate medical purpose and then, the rest of it, written by a practitioner in the usual course of professional practice. But verification is much more than the nuts and bolts that we just went through about do you -- did you write this prescription and so forth. I mean, in my personal experience, if a physician is writing --
MR. SCHMIDT: Objection, your Honor. He is testifying as an expert.
MR. TEHRANI: I believe he is, your Honor.
THE COURT: Overruled.
You may answer.
THE WITNESS: I'm sorry?
THE COURT: You may continue.
A. In my experience, every bad pharmacy that we took out, one of the things -- I take that back, I'm sorry, not every. The majority of the bad pharmacies that we investigated, one of their defenses was we always called the doctor. Well, of course if the doctor is writing bad prescriptions, they're going to say I wrote it. They're not going to say it's a bad

prescription. So calling and verifying is not adequate. The pharmacist has to go further.

Q. You were asked some questions yesterday, I believe by Mr. Schmidt, about whether a pharmacy would be able to look at patient prescribing records for a new patient. Do you remember those questions?

A. Yes.

Q. And I believe your testimony was that from the pharmacy's own records, they of course would not be able to see anything about that particular patient because, by definition, the patient is new?

A. That is correct.

Q. Are there other ways for a pharmacy to review the prescribing history for a new patient?

A. Yes, there are.

Q. Could you please explain what those are?

A. Most states have a prescription monitoring program in place that collects prescriptions filled for citizens of that state for controlled substances. It does not collect information on noncontrolleds -- blood pressure, antibiotics, and so forth, but it does collect information on controlled substances. So a pharmacist has -- pharmacists and physicians have access to that database where they can verify if the patient has been going elsewhere within that state.

Now there is, through the National Association of

Boards of Pharmacy, there is a prescription monitoring program, Interconnect Program, in place where not only can a pharmacist get information from their own state but in 30 states, so far, they can get information from other states as well. So the example I'm most familiar with is an Ohio pharmacist can now check to see if a patient has also got controlled substances in West Virginia, Kentucky, Indiana or Michigan so they can get a wider appreciation of that patient's activities. New Jersey is included in that Interconnect Program.

Q. You were also asked some questions about the argument that there is an undertreatment of pain in the United States. Do you remember those questions?

A. Yes, I do.

Q. Where does the United States rank in the dispensing of hydrocodone with respect to the rest of the world?

A. Hydrocodone -- I'm sorry, the United States uses 99 percent of the world's supply of hydrocodone.

Q. And you were also asked some questions about pharmacists being unwilling to dispense controlled substances. Do you remember those questions?

A. Yes, I do.

Q. Is that a prevalent problem?

A. It is not prevalent. It does exist in with individual pharmacists.

Q. Is the abuse of pain medication a prevalent problem in the

United States?
A. It is a huge problem. In 2013 we had 16,000 people die of accidental overdose due to opiates alone.
Q. Is the abuse of oxycodone specifically a prevalent problem in the United States?
A. It's -- oxycodone is one of the major drugs involved in that problem. Florida particularly had major problem with this. They had well over a thousand deaths from accidental oxycodone over the last -- each year for several years in a row.
Q. What is your basis of knowledge of that problem?
A. Well, the death reports in Florida come from the Florida medical examiners who do -- who gather statistics. The 16,000 deaths has actually been reported by Centers for Disease Control and several other organizations that collect data. The 90 percent comes from the international organization responsible for monitoring the flow of opiates throughout the world, and all major countries report their purchases and sales through that International Narcotics Control Board. I'm sorry. I meant to include that.
Q. What about in your personal experience as the Executive Director of the Ohio Board of Pharmacy?
MR. FISHER: Judge, I object to this continued line of questioning under 403 grounds.
THE COURT: Will you step up, please.

(At the sidebar)

THE COURT: Don't explain your objections.

MR. FISHER: I'm just saying this talk about all the people that are dying from oxycodone use, to go into detail has some slight probative value in this case about whether our clients were actually filling medically necessary prescriptions, but the prejudice is huge and it really does not have much probative value to the contested issues of facts in this case. So to keep going on and on about that I think is enough.

MR. TEHRANI: Your Honor, the defense has presented this case as their clients being the white knights --

MR. FISHER: No, we haven't.

MR. TEHRANI: -- who stepped in to address a significant overreaction by the DEA which has resulted in pharmacists being unwilling to dispense medication, wholesalers being unable to supply medication, and people with intractable chronic pain being unable to address that pain.

This expert witness is qualified and entitled to testify about what the real issues related to abuse because of pain medication in the United States are.

THE COURT: Do you have much more on this?

MR. TEHRANI: No.

THE COURT: Overruled.

(Continued on next page)

(In open court)

THE COURT: Continue.

BY MR. TEHRANI:

Q. Mr. Winsley, I had asked you about whether there was anything in your personal experience as the Executive Director of the Ohio Board of Pharmacy that informed your knowledge of the problem of pain killer abuse in the United States.

A. Absolutely we had a major problem, still do, in Ohio. The Ohio River corridor of West Virginia, Kentucky and Ohio several years ago was known as the OxyContin capital of the world. We have whole communities in northern Kentucky and southern Ohio where everybody abuses hydrocodone or oxycodone. We had multiple cases of our own dealing with doctors who set up operations. One in particular, a doctor in northeast Ohio --

MR. CHECKMAN: Your Honor, I am going to object to this as improper redirect examination.

THE COURT: Overruled.

You may continue.

THE WITNESS: Thank you.

A. A doctor who set up operations in northeast Ohio. We monitored the parking lot initially. 80 percent of the patients were from Kentucky. They drove 250 miles one way to get there. The doctor wrote prescriptions for hydrocodone. They wrote in such quantities that they were so busy they would call the prescriptions to the pharmacy. The pharmacy had

blanks preprinted as either green hydrocodone or blue hydrocodone, the preference choice, and the doctor was convicted of drug trafficking. The pharmacists were subjected to --

MR. FISHER: Your Honor, I object to the specific incident that is not what we are here for.

THE COURT: So the witness is explaining the basis of his knowledge. Of course, what he is describing has no direct bearing on this particular case. He is not discussing the individuals in this case. It is a wholly unrelated case, but he is just giving background so that you may understand his conclusions.

A. I'll just talk about a couple of other things, then. We also had nine pill mills located in a small town in Portsmouth, Ohio, called Portsmouth Ohio. Several of the doctors that we investigated had started in Florida and moved to Ohio, and one of them moved out of Portsmouth up to another city in Ohio. The end result of that was that we in Ohio, our legislature passed a pain management bill, and the result of that was the nine pill mills disappeared. Two of them had -- were convicted, the others moved out.

But we've had a major problem with opiates in Ohio. Huge quantities of hydrocodone and oxycodone coming through our prescription monitoring program, so we know how many doses are being prescribed to patients in Ohio. Just as an example, for

hydrocodone, for several years there has been over 250 million doses prescribed of hydrocodone for our 11 million population and that's everybody in the state. There were several counties down along that Ohio River corridor where the consumption on average by county was huge.

So, yes, I have a great amount of personal experience with the opiate epidemic that's going on.

Q. Mr. Winsley, in your expert opinion, is that epidemic of drug abuse more or less of a problem than pharmacists being unwilling to dispense oxycodone?

MR. FISHER: Objection.

THE COURT: Overruled.

You may answer.

A. It is way more of a problem. As I mentioned, the 16,000 deaths in the country from accidental overdose, the fact that opiate abuse is an epidemic. I do know that we have some pharmacists who, I am ashamed to say, don't think about their patients first and refuse to fill, but I also know that there are an overwhelming number of pharmacists who put their patients first and fill the prescriptions that their patients need.

THE COURT: So, again, members of the jury, the witness is not discussing the facts in this case. He is talking about his knowledge and giving examples. But there are no allegations in this case involving the death of a patient.

And so when listening to his testimony, understand that he is speaking about other matters that are not related specifically to this case.

MR. TEHRANI: No further questions, your Honor.

THE COURT: Recross.

RECROSS-EXAMINATION

BY MR. SCHMIDT:

Q. Mr. Winsley, isn't it a fact that there are approximately 25 million Americans who suffer from chronic pain on a daily basis?

A. I can't verify that.

Q. Oh, OK. You cited statistics that apparently you read from other places. So I'm not asking you to verify that. I'm asking you, have you read that anywhere during the course of your preparation for testifying in cases or as a director of the Ohio Board of Pharmacy?

A. No.

Q. Have you read anywhere about how many people in our country suffer from chronic pain on a daily basis?

A. I have not read numbers.

Q. Are you saying that numbers don't exist out there or that you haven't made an effort to read numbers?

A. Neither. I mean, I have not read any specific numbers.

MR. SCHMIDT: May I have a moment, your Honor?

(Pause)

Q. Have you ever heard of an organization called Public Health Watch?
A. Yes.
Q. Could you tell us what that organization is?
A. I've heard of them. I don't know what their background is.
Q. Have you read anything that they have published?
A. Not that I recall.
Q. You've testified in criminal cases for the prosecution, haven't you?
A. Yes.
Q. And you have been -- and you provided us with details of the terrible problem with drug abuse in our country, haven't you?
A. Yes.
Q. Have you made any effort to examine the information of the other side, the people who are suffering?
A. I have read articles.
Q. And it is your testimony you have read not a single article that put a general number on the people in this country who have suffered from chronic pain on a daily basis?
A. Not that I recall.
Q. And besides chronic pain, right, have you read about the number of people who have severe pain but they suffer it less likely, being approximately 40 million people?
MR. TEHRANI: Objection, your Honor. Can we have that

reasked?

THE COURT: Can you rephrase that, please?

BY MR. SCHMIDT:

Q. Have you seen any data that indicates that approximately 40 million Americans suffer from severe pain but not on a daily basis?

A. No.

Q. Wouldn't it be Ohio Board -- withdrawn.

Have you gone to any of the Florida Board of Pharmacy meetings in the last ten years?

A. No.

Q. Have you gone to any county Board of Pharmacy in Florida in the last ten years?

A. There is no such thing that I know of.

Q. You have never heard of Broward County Board of Pharmacy?

A. No.

Q. Have you talked to -- withdrawn.

Now, there are some very specific requirements that an actual prescription must have on it, is that correct?

A. Yes.

Q. When we were talking -- when you were being questioned and answering questions on cross-examination of Mr. Fisher, what you tried to make clear was that there are certain things that are necessary and certain things that are a good idea, right?

(Pause)

Do you want me to rephrase the question?
A. Yes. I think you had better, please.
Q. Making sure that certain information on a prescription is necessary and required, is that right?
A. Yes.
Q. And those things are actually listed?
A. Yes.
Q. They are listed in the DEA, right?
A. The Code of Federal Regulations, yes.
Q. But how to determine whether the prescription is written for a legitimate medical purpose in the usual course of professional practice is not written in that Code, right?
A. How to determine?
Q. Yes.
A. No, it is not.
Q. Now, it's your testimony that it really is a waste of time to call a doctor -- a doctor's office, or even the doctor, to verify the prescription because every doctor is going to say, yes, its a valid prescription?
MR. TEHRANI: Objection. Mischaracterizes his testimony.
THE COURT: Overruled.
You may answer.
A. Actually, no. That's not my testimony in complete. That's not what I testified to.

Q. Well, you testified that if a pharmacist takes a look at a prescription, the prescription looks valid on its face, that there's really -- and he has no questions as to the prescription itself, that calling the doctor's office is not useful; is that what you said?
A. That's closer.
Q. Let me make it precise. What did you say?
A. If the pharmacist asks the question, one of the things they need to do is call and verify that the script was written, but that in itself does not verify that the prescription is legitimate. So if all they do is call every time on a controlled substance prescription, that is meaningless because we know that the doctors who write prescriptions not for a legitimate medical purpose are going to verify that they did write the prescription.
Q. So a person walks into a Walgreens pharmacy and has never been there before and gives a prescription for a controlled substance, a pain medication, a Schedule II, right, if the prescription is valid, his identification is valid, and the pharmacy checks the PMP that he has either a history of that medication or there is no history there yet, there is really nothing that that pharmacist can do to satisfy what you consider what's necessary before filling that prescription; is that right?
A. No.

Q. What could that pharmacist do at that time?
A. It depends upon whether or not the pharmacist knows the doctor, do they have other prescriptions from the doctor, do they recognize the signature. If so, then they don't need to call and say did you write it. Pharmacists are pretty good at that.
You said either they do or they don't have a history in the PMP in your question. Well, if they do, then maybe they need to call the doctor if that history is extensive. If they have no history in the PMP, if they recognize the doctor's signature, if the prescription seems to be legitimate, if they have done all their other duties in terms of checking the profile, there is no need for them to call.
Q. So you start with what if he doesn't know the doctor, he should check to see the doctor is legitimate?
A. Yes.
Q. Say if the person on the PMP 30 to 60 days earlier had a similar script that was filled in a nearby Walgreens, is there something else that that doctor should do -- that pharmacist should do?
A. If it's the same doctor?
Q. The same doctor.
A. Probably not.
Q. And so what else would need to be done?
A. I think I've covered it --

Q. So basically we just went through would satisfy the doctor -- would satisfy the pharmacist he should fill it?
A. If all of those factors were positive, yes.
Q. What if he doesn't recognize the doctor or the doctor is 50 miles -- the address is like 50 miles south of the pharmacy, what should he do?
A. If he doesn't recognize --
Q. Other than what we've already said.
A. Well, that's pretty much it. If he has any questions, he should call the doctor, but he could do most of those other steps that we talked about.
Q. Now, if a prescription for diabetic medication is written by a doctor who has a specialty in treating diabetes, would it be fair to say that a pharmacist would have less reason to make great efforts to verify everything other than to make sure it is valid, the script?
MR. TEHRANI: Objection, your Honor. This is well beyond the scope of redirect. We are redoing cross-examination now.
THE COURT: Sustained.
MR. SCHMIDT: Excuse me?
THE COURT: Sustained.
MR. SCHMIDT: Your Honor, Mr. Fisher went into this on his cross-examination, right, and I am going further, asking questions relating to the things that he asked on

cross-examination.

THE COURT: Step up, please.

(Continued on next page)

(At the sidebar)

THE COURT: So what was it that Mr. Fisher went into concerning noncontrolled substances?

MR. SCHMIDT: No. On what needs to get done to satisfy the pharmacist under certain reasons before he fills the prescription. He went through the whole thing about verifying stuff and went through some things and, no disrespect to Mr. Fisher, I think that there are things that needed to be followed up based on the questions and answers that I did not raise, that he raised. So I should have the ability to complete what I think would be necessary based on some of the points that he raised.

THE COURT: So my recollection is that he covered controlled substances and you were just talking about diabetes.

MR. SCHMIDT: I just used that as an example. I will do another example. I will do another controlled substance.

MR. TEHRANI: Your Honor, that is not the way this works. If the government had not redirected, Mr. Schmidt would not have an opportunity to stand up and redo his entire cross-examination. I don't think Mr. Schmidt can realistically come before this Court and say that he has been unfairly limited in the length and scope of his cross-examinations. We have been through this for hours.

THE COURT: What exactly do you plan to cover?

MR. SCHMIDT: I plan to cover what is necessary to

verify under the certain circumstances that is relevant to this case, right, that Mr. Fisher began going into and I don't think he completed it. It is not a lot. I apologize for using a noncontrolled substance as an example but I will go into it with a controlled substance.

THE COURT: All right. I think you have covered the area. I am going to allow you to ask some questions. I hope that they will be pointed and that there won't be long pauses in between the questions.

MR. SCHMIDT: I will try my best not to have long pauses, your Honor.

(Continued on next page)

(In open court)

BY MR. SCHMIDT:

Q. Would a pharmacist expect to receive prescriptions that was written by a physician in a pain clinic that would include opioids?

A. Yes.

Q. Would they expect prescriptions that included ibuprofen?

A. Possibly.

Q. Would they expect prescriptions written for constipation?

A. Yes.

Q. Now, of those three that I mentioned, only one is a controlled substance, right?

A. That is correct.

Q. And it is the controlled substance that requires the little bit more -- the additional effort on the part of the pharmacist to verify, is that right?

A. Yes.

Q. Now, if it is written by a physician that the pharmacist has previously filled for another patient and knows that that physician is licensed and working at a pain clinic and receives a prescription for pain medication from an individual, what else should that pharmacist do before filling that prescription other than the things that we've just discussed?

A. Still has to look at the dose, the directions for use, the history of the physicians prescribing that they have available

to them, the patient's history, all of those things that I discussed previously.
Q. And for a patient that has one previous prescription filled that they could find on the PMP for opioids either the month before or two months before for the same amount, would that require additional verification?
A. For the part of the patient, probably not. The physician prescribing practices still are something that's of concern.
Q. And you, your opinion, is that a pain clinic that provides -- predominantly treats a patient with opioids is automatically in your mind suspicious and requires a lot more verification for a pharmacist; is that your -- would that be an accurate statement?
A. Not completely, no.
Q. What is the "not completely" part?
A. That treats patients only with drugs, including opioids, but the keyword being "only."
Q. Now, how would a pharmacist know that --
A. Talk to the patient -- oh, I'm sorry.
Q. -- where he only gets prescriptions to fill and he doesn't know what other things that that doctor may do?
A. Talk to the patient. One of the things he is required to do is to talk to the patient to obtain a profile, including disease states and other treatments. And so if the pharmacist has a concern, that's one of the things they would want to ask

the patient.
Q. And if the patient says that I don't know what else the doctor does, I went in there, I was examined, and he gave me a prescription for this; would that satisfy the pharmacist?
A. No.
Q. How is he going to find out what else the doctor does?
A. He is going to ask the patient and he will ask two or three patients, and if none of them have a clue what physical therapy is or what massage therapy or relaxation techniques or electrical stimulation, if the clinic is not doing anything but writing drugs, I've already testified that makes it questionable in my mind.
Q. A long-term chronic, severe pain patient, wouldn't that -- withdrawn.
Do long-term chronic, severe pain patients -- withdrawn.
Is it appropriate or inappropriate in your mind that a long-term chronic, severe pain patient would be receiving opioids for an extended period of time?
A. It could be appropriate.
Q. Now, you did talk about the PMPs and the nationwide -- I forgot what word you used -- the nationwide program now for what these PMPs are?
A. Yes, Interconnect.
Q. When did that start?

A. It started shortly before I retired in 2011, and it's been expanding since then.
Q. When you say "expanding," because many states did not join that right away, did they?
A. They were not able to, right.
Q. And, in fact, there was a whole big discussion in the State of Florida where the Governor of the State of Florida did not want to have a PMP for many, many years, is that right?
A. That is absolutely correct.
Q. In fact, the first time that Florida started developing a PMP was in 2013, wasn't it?
A. I don't remember the date but it was just recent.
Q. So when you told us now, on redirect examination, you explained what a pharmacist should do in examining a PMP to find out the history of that patient, it had no meaning for the State -- for the patients in the State of Florida in 2011, 2012 and until it got started in 2013, isn't that right?
A. Oh, yes.
Q. So someone treating -- so a pharmacist had no -- wherever they are located, in the State of Florida or the State of New Jersey, had no way to check on a PMP for a patient who saw a doctor in the State of Florida, is that right?
A. If the patient lived in Florida, that is correct.
Q. The patient filled the prescription in Florida.
A. I'm sorry.

Q. No matter where the patient lived, right?
A. Yes. I believe that's correct.
Q. It is the pharmacist who is supposed to put the information in the PMP, is that right?
A. Well, the pharmacy system.
MR. SCHMIDT: I have no further questions.
MR. FISHER: Just very briefly.
THE COURT: OK.
RECROSS-EXAMINATION
BY MR. FISHER:
Q. When Mr. Tehrani got up and asked you some questions, we heard a lot about some of your life experience, right?
A. Yes.
Q. Things that you know, right?
A. Yes.
Q. Things that have obviously shaped your view on this subject, correct?
A. Yes.
Q. Have you ever worked in Florida in the last five years?
A. We had one of those DEA talks in Florida to over 1200 pharmacists.
Q. How long were you there on that occasion?
A. Two days.
Q. Besides those two days, have you ever worked in Florida over the last five years?

A. I have not.
Q. Have you ever reviewed the patient charts in this case?
A. No. I already said that.
Q. Have you ever reviewed the prescriptions that were filled by Plainfield Pharmacy in this case?
MR. TEHRANI: Objection. We have been over this.
MR. FISHER: I have three more questions.
THE COURT: Overruled.
You may answer.
A. No.
Q. Have you ever inspected the doctors' offices or the pain clinics that were involved in this case?
A. No.
Q. Have you ever been to Medical Specialists, that pain clinic, that particular one in south Florida?
A. No.
Q. Have you ever gone down to south Florida in the last five years and actually talked to the patients, the people that were suffering from chronic, severe pain?
A. No.
MR. FISHER: Thank you.
THE COURT: All right. Thank you, sir. You may step out.
THE WITNESS: Thank you.
(Witness excused)